

Audit

Report



ARMED SERVICES BLOOD PROGRAM READINESS

Report No. D-2001-059

February 23, 2001

Office of the Inspector General
Department of Defense

Form SF298 Citation Data

Report Date ("DD MON YYYY") 23Feb2001	Report Type N/A	Dates Covered (from... to) ("DD MON YYYY")
Title and Subtitle Armed Services Blood Program Readiness		Contract or Grant Number
		Program Element Number
Authors		Project Number
		Task Number
		Work Unit Number
Performing Organization Name(s) and Address(es) OAIG-AUD (ATTN: AFTS Audit Suggestions) Inspector General, Department of Defense 400 Army Navy Drive (Room 801) Arlington, VA 22202-2884		Performing Organization Number(s) D-2001-059
Sponsoring/Monitoring Agency Name(s) and Address(es)		Monitoring Agency Acronym
		Monitoring Agency Report Number(s)
Distribution/Availability Statement Approved for public release, distribution unlimited		
Supplementary Notes		
Abstract <p>This audit is the first in a series of audits concerning the Armed Services Blood Program. The Armed Services Blood Program mission is to provide quality fresh and frozen blood products, blood substitutes, and services for all worldwide customers in peacetime and war. In FY 1999, blood program costs, including personnel, operations and maintenance, and testing were \$26.7 million. The Armed Services Blood Program consists of 11 categories of activities, including the Armed Services Blood Program Office, Military Department blood program offices, unified command blood program offices, blood program organizations within the Military Departments, and military treatment facilities. Each of these activities is critical to the successful collection, storage, and distribution of blood products. The frozen blood program was established to allow prepositioning of frozen blood products within unified commands and aboard ship. Pre-positioned repositories provide blood products during the initial stages of a contingency operation or war until liquid products can be supplied from the continental United States. Frozen red blood cells have a Food and Drug Administration-approved shelf life of 10 years. However, frozen red blood cells have a DoD-approved shelf life of up to 21 years for readiness purposes.</p>		
Subject Terms		

Document Classification unclassified	Classification of SF298 unclassified
Classification of Abstract unclassified	Limitation of Abstract unlimited
Number of Pages 73	

Additional Copies

To obtain additional copies of this audit report, visit the Inspector General, DoD, Home Page at www.dodig.osd.mil or contact the Secondary Reports Distribution Unit of the Audit Followup and Technical Support Directorate at (703) 604-8937 (DSN 664-8937) or fax (703) 604-8932.

Suggestions for Future Audits

To suggest ideas for or to request future audits, contact the Audit Followup and Technical Support Directorate at (703) 604-8940 (DSN 664-8940) or fax (703) 604-8932. Ideas and requests can also be mailed to:

OAIG-AUD (ATTN: AFTS Audit Suggestions)
Inspector General, Department of Defense
400 Army Navy Drive (Room 801)
Arlington, VA 22202-4704

Defense Hotline

To report fraud, waste, or abuse, contact the Defense Hotline by calling (800) 424-9098; by sending an electronic message to Hotline@dodig.osd.mil; or by writing to the Defense Hotline, The Pentagon, Washington, DC 20301-1900. The identity of each writer and caller is fully protected.

Acronyms

AFB	Air Force Base
ASBPO	Armed Services Blood Program Office
ASWBPL	Armed Services Whole Blood Processing Laboratory
BDC	Blood Donor Center
BTC	Blood Transshipment Center
CONUS	Continental United States
FDA	Food and Drug Administration
JBPO	Joint Blood Program Office
SBPO	Service Blood Program Office
USEUCOM	U.S. European Command
USPACOM	U.S. Pacific Command



INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-4704

February 23, 2001

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE
(FINANCIAL MANAGEMENT AND COMPTROLLER)
DIRECTOR, JOINT STAFF
NAVAL INSPECTOR GENERAL
AUDITOR GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Audit Report on Armed Services Blood Program Readiness
(Report No. D-2001-059)

We are providing this report for review and comment. This report is the first in a series of reports to be issued on the Armed Services Blood Program. We considered management comments on a draft of this report when preparing the final report.

DoD Directive 7650.3 requires that all recommendations be resolved promptly. As a result of management comments, we modified Recommendation B.2. to clarify our intention. The Armed Services Blood Program Office comments were fully responsive; however, the Joint Staff comments were nonresponsive. The Army, the Navy, and the Air Force comments were partially responsive. Therefore, we request the Joint Staff provide comments on Recommendation B.3. In addition, we request the Army provide additional comments on Recommendations B.1.; the Navy provide additional comments on Recommendations A.3., B.1., and B.2.; and the Air Force provide additional comments on Recommendation B.2. We request that management provide comments by April 23, 2001.

We appreciate the courtesies extended to the audit staff. Questions on the audit should be directed to Mr. Michael A. Joseph (757) 766-9108 (mjoseph@dodig.osd.mil) or Ms. Betsy Brilliant at (703) 604-8875 (DSN 664-8875) (bbrilliant@dodig.osd.mil). See Appendix F for the report distribution. The audit team members are listed inside the back cover.

David K. Steensma
David K. Steensma
Deputy Assistant Inspector General
for Auditing

Office of the Inspector General, DoD

Report No. D-2001-059

February 23, 2001

Project No. D2000LF-0028

(formerly Project No. 0LF-0106)

Armed Services Blood Program Readiness

Executive Summary

Introduction. This audit is the first in a series of audits concerning the Armed Services Blood Program. The Armed Services Blood Program mission is to provide quality fresh and frozen blood products, blood substitutes, and services for all worldwide customers in peacetime and war. In FY 1999, blood program costs, including personnel, operations and maintenance, and testing were \$26.7 million.

The Armed Services Blood Program consists of 11 categories of activities, including the Armed Services Blood Program Office, Military Department blood program offices, unified command blood program offices, blood program organizations within the Military Departments, and military treatment facilities. Each of these activities is critical to the successful collection, storage, and distribution of blood products.

The frozen blood program was established to allow prepositioning of frozen blood products within unified commands and aboard ship. Pre-positioned repositories provide blood products during the initial stages of a contingency operation or war until liquid products can be supplied from the continental United States. Frozen red blood cells have a Food and Drug Administration-approved shelf life of 10 years. However, frozen red blood cells have a DoD-approved shelf life of up to 21 years for readiness purposes.

Objectives. The overall objective of the audit was to determine whether management and administration of the Armed Services Blood Program is adequate to ensure quality blood products are properly handled and controlled during peacetime and wartime. This report also addresses the readiness of the Armed Services Blood Program. Future audits will address blood program information systems and operating efficiencies. We also reviewed the adequacy of the management control programs as they applied to the audit objective.

Results. The DoD needs to improve readiness management of the Armed Services Blood Program. The DoD blood program offices did not properly manage the frozen red blood cell inventory of the Armed Services Blood Program. Of the 33 blood program organizations that provided inventory data, 18 did not meet their wartime inventory requirements. As a result, DoD did not have accurate frozen red blood cell inventory reporting and accountability, which could impact major theater war operations (finding A).

In addition, DoD needs to improve mobilization planning and training for the Armed Services Blood Program. Of the three Military Department blood program offices, two did not prepare sufficient mobilization planning documents. Of the 15 blood program organizations visited, 9 did not have written, approved mobilization plans that would clearly identify actions needed by the organizations in the event of a contingency. In addition, 13 of the 15 blood program organizations visited have mobility missions and 6 of those did not have complete organization-level training. Only one of the unified commands visited had the blood program organizations within its command involved in

joint- or unified command-level training exercises. As a result, the blood program organizations may not be able to properly activate in the event of a mobilization (finding B). See Appendix A for details on the management control program as it relates to frozen blood inventory management, mobilization planning, and training.

Summary of Recommendations. We recommend that the Director, Armed Services Blood Program Office, issue policy that defines the various categories of blood unit status, requires reporting of the different categories, and identifies the use and disposition of each category. The Director should also prepare a plan for meeting future testing requirements and establish controls to ensure frozen blood inventory requirements are met. We further recommend the Assistant Secretary of Defense (Health Affairs) study the feasibility of using frozen blood during peacetime. We recommend that the Surgeons General budget to replace untested and expired red blood cell inventory, ensure blood program organizations develop mobilization plans, and ensure blood program organizations adequately prepare and train for their mobility missions. Further, we recommend that the Joint Staff incorporate training in blood program distribution and processing into joint- and unified command-level exercises.

Management Comments. The Armed Services Blood Program Office partially concurred with our findings and recommendations. They acknowledged that management of the frozen red blood cell inventory needed improvement. However, they disagreed that the current inventory was insufficient to support contingency requirements because DoD allows frozen red blood cells more than 10 years but less than 21 years old to be used in a contingency. They concurred with our recommendations to issue policy regarding standard identification, use, and disposition of frozen red blood cells; establish a plan when new tests are required; and study the use of frozen blood in peacetime. However, they indicated that a major impediment to a successful program is insufficient staffing. In addition, funding will be needed to replace existing inventory.

The Military Departments concurred with the recommendations to fund for the replacement of untested and expiring inventory and to require blood program organizations to prepare mobilization plans and train in their mobility mission. The Joint Staff commented that there was a joint training exercise in 2000 for blood distribution and there was a first ever class in 2000 for five Area Joint Blood Officers.

Audit Response. As a result of management comments, we modified the report to allow for contingency purposes frozen red blood cells that are untested, but appropriately labeled, or more than 10 years but less than 21 years old. However, we believe that DoD should work toward a frozen blood inventory composed entirely of fully tested, nonexpired red blood cell units. While our recommendations did not change, we acknowledge that replacing all untested and expired blood is difficult at this time.

The Armed Services Blood Program Office comments were fully responsive; however, the Joint Staff comments did not adequately address the recommendations. The Army, the Navy, and the Air Force comments were partially responsive. Therefore, we request the Joint Staff provide comments on implementing joint- and command-level blood-related training. In addition, we request the Army provide additional comments on controls it will use to ensure training is accomplished. We request the Navy provide additional comments on funding inventory replacement, implementing mobilization planning and training requirements, and establishing mobilization planning documents. Additionally, we request the Air Force provide additional comments on identifying mobilization sources at blood program organizations. We request management provide comments by April 23, 2001.

Table of Contents

Executive Summary	i
--------------------------	---

Introduction

Background	1
Objectives	3

Findings

A. Frozen Red Blood Cell Inventory Management	4
B. Mobilization Planning and Training	18

Appendices

A. Audit Process	
Scope and Methodology	28
Management Control Program Review	29
Prior Coverage	30
B. Armed Services Blood Distribution System	31
C. Glossary	32
D. Blood Program Policies	34
E. Future Blood Program Initiatives	37
F. Report Distribution	40

Management Comments

Armed Services Blood Program Office	43
Joint Staff	53
Department of the Army	55
Department of the Navy	57
Department of the Air Force	63
U.S. Pacific Command	66

Background

Armed Services Blood Program. The Armed Services Blood Program (the Blood Program) was formally established by Presidential Order in 1952 as the Military Blood Program, part of the National Blood Program. The Blood Program's mission is to provide quality blood products, blood substitutes, and services for all worldwide customers in peace and war. In FY 1999, blood program costs, including personnel, operations and maintenance, and testing were \$26.7 million.

Blood Program Activities. The Blood Program consists of 11 categories of activities, including blood program offices¹ and blood program organizations.² Each of these activities is critical to the successful collection, storage, and distribution of blood products. See Appendix B for a depiction of how the blood program activities interact to form the blood distribution system. See Appendix C for a glossary of key terms, including a description of the blood program activities.

Blood Program Management. The primary blood program offices responsible for the management of the Blood Program are the Armed Services Blood Program Office (ASBPO), the Service Blood Program Offices (SBPOs), and the Joint Blood Program Offices (JBPOs).

Armed Services Blood Program Office. The ASBPO is a joint health agency chartered to monitor the implementation of blood program policies established by the Assistant Secretary of Defense (Health Affairs) and to coordinate the blood programs of the Military Departments and unified commands. The Army Surgeon General, on behalf of the Secretary of the Army, serves as the Executive Agent for the ASBPO and provides administrative support and staff supervision. The ASBPO is required to coordinate day-to-day activities of the Blood Program, establish blood quotas for the Military Departments, and ensure frozen blood products are prepositioned. The ASBPO relies on the SBPOs and the JBPOs to manage the Military Department and unified command blood programs, respectively, during peacetime and wartime.

Service Blood Program Offices. The SBPOs manage the individual Service blood programs and are responsible for establishing Service-unique quotas for readiness and identifying mobilization requirements. The primary focus of the SBPOs is peacetime blood program management at the military treatment facilities. More specifically, the focus has been on Food and Drug Administration (FDA) licensure and compliance issues in response to increased regulatory requirements established by the FDA.

¹For this report, we considered the blood program offices as the Armed Services Blood Program Office, the Service blood program offices, and the unified command joint blood program offices.

²For this report, we considered the blood program organizations as the operational activities within the Blood Program, including the armed services whole blood processing laboratories, blood donor centers, blood product depots, blood transshipment centers, and transportable blood transshipment centers.

Joint Blood Program Offices. The JBPOs serve as the overall manager for blood and blood components within the unified commands by managing and coordinating the total joint blood product requirements and capabilities. The JBPOs primarily focus on in-theater readiness requirements. Area JBPOs may be required to assist the JBPOs for specified geographic areas within the unified command.

DoD Blood Program Policies. DoD Instruction 6480.4, “Armed Services Blood Program Operational Procedures,” August 5, 1996, is the primary policy for the Blood Program. Each Military Department and most of the unified commands have issued policies that implement the DoD policy. The policies are summarized in Appendix D.

Blood Products. Blood is considered the whole blood collected from a single donor and can be broken down into three major components: red blood cells, plasma, and platelet concentrates. Freezing red blood cells and plasma is approved by the FDA. Freezing platelets has not been approved.

- **Red blood cells.** Glycerol is added to the red blood cells before freezing. When the red cells are thawed, the glycerol is removed through a deglycerolization process. Frozen red blood cells have an FDA-approved shelf life of 10 years.³ Thawed, deglycerolized red blood cells have a shelf life of 24 hours.
- **Plasma.** Thawed plasma can be immediately transfused because no chemicals have to be removed. Frozen plasma has an FDA-approved shelf life of 1 year or 7 years depending on storage temperature. Thawed plasma has a shelf life of 24 hours.

Frozen Blood Program. The frozen blood program was established to allow prepositioning of frozen blood products within the unified commands and aboard ship. Pre-positioned repositories provide blood products during the initial stages of a contingency operation or war until liquid products can be supplied from the continental United States (CONUS). The JBPOs, who determine the frozen blood requirements for the unified commands, plan for the use of frozen blood products during the first 10 days of a contingency operation.

The majority of the frozen blood product inventory is maintained in four blood product depots—three located in the U.S. Pacific Command (USPACOM) and one in the U.S. European Command (USEUCOM). The Armed Services Whole Blood Processing Laboratories (ASWBPLs) are also required to maintain a supply, primarily as a supplement to the blood product depots.

Blood Usage Planning. The DoD uses the Medical Analysis Tool, an automated medical support system, to determine blood requirements during contingencies. The Medical Analysis Tool system establishes blood requirements based on the population at risk and estimated casualty rates.

³The DoD has requested FDA approve extending the frozen red blood cells shelf life to 17 years. See Appendix E for details.

The Services provide the data to the unified commands, who incorporate the Service-specific data into their mobilization plans. Unified command blood requirements are provided to ASBPO and the Joint Staff, who plan and program for blood support.

Objectives

The overall objective of the audit was to determine whether the management and administration of the Blood Program is adequate to ensure quality blood products are properly handled and controlled during peacetime and wartime. This audit is the first in a series of audits concerning the Blood Program. This report discusses concerns with the readiness of the Blood Program. Future audits will address blood program information systems and operating efficiencies. We also reviewed the adequacy of the management control programs of the ASBPO and the Military Department Surgeons General offices, as they applied to the audit objective. See Appendix A for a discussion of the audit scope and methodology, review of the management control programs, and prior coverage related to the audit objectives.

A. Frozen Red Blood Cell Inventory Management

The DoD blood program offices did not properly manage the frozen red blood cell inventory of the Armed Services Blood Program. Of the 33 blood program organizations that provided inventory data, 18 did not meet their inventory requirements. This occurred because the ASBPO did not provide a clear policy that standardized identification, use, and disposition of the frozen red blood cell inventory. In addition, the ASBPO did not establish a written plan for replacing or rotating untested or expired inventory. As a result, DoD did not have accurate frozen red blood cell inventory reporting and accountability which could impact major theater war operations.

Composition of the Frozen Red Blood Cell Inventory

For this report we grouped the frozen red blood cell inventory into three types of units of blood—fully tested, nonexpired units; HIV-1 p24 antigen⁴ untested units; and expired units. The fully tested, nonexpired units are those units tested in accordance with current FDA requirements and do not exceed the 10-year frozen shelf-life restriction established in 1987 by the FDA. The HIV-1 p24 antigen untested units are those units frozen before implementing the antigen test and not subsequently tested. The expired units are those units that have exceeded the 10-year frozen shelf-life requirement. However, the DoD allows that both untested units and expired units may be used for contingency purposes.

Untested Units. DoD retains untested units in the event of a contingency as allowed by the FDA in its April 8, 1996 letter to the Director, ASBPO. Specifically, the letter states that if testing is not available, the unit should be labeled with a “Caution” statement. The letter further states that all units so labeled should “only be used in cases of emergency, including military need.” The FDA letter to the Director, ASBPO, was sent to supplement the requirements in its August 8, 1995 memorandum, “Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen” concerning HIV-1 antigen testing. As a result of the FDA memorandum, military blood inventory storage facilities were tasked, in accordance with ASBPO memorandum, “Donor Screening for HIV-1 Antigen,” October 4, 1995, to test their stored frozen red blood cell units using the HIV-1 p24 antigen test. However, a portion of the frozen red blood cell inventory could not be tested for the HIV-1 p24 antigen because there were no serum cryovials⁵ available for the additional test or the cryovials were inadequate for HIV-1 p24 antigen testing. The untested units are being retained for contingency purposes.

⁴The HIV-1 p24 antigen test, implemented in 1995, reduced the window period between an individual’s exposure to HIV and a positive test result, lowering it from 25 days to 16 days.

⁵Cryovials contain small quantities of blood from the unit that are generally stored with the unit to allow for future testing.

Expired Units. DoD has established different shelf lives for frozen red blood cell units, depending on whether the units will be used during peacetime or in the event of a contingency. For peacetime purposes, the frozen red blood shelf life is 10 years, as approved by the FDA. However, for readiness purposes, the frozen red blood shelf life is currently 21 years. Joint Publication 4.02-1, “Joint Tactics, Techniques, and Procedures for Health Service Logistics Support in Joint Operations,” October 6, 1997, and Army Field Manual 8-55, “Planning for Health Service Support,” September 9, 1994, allow frozen red blood cells with a shelf life of up to 21 years to be used to meet wartime requirements. The extension was given by the Defense Medical Standardization Board in the publication, “Deployable Medical Systems Policies and Guidelines Treatment Briefs,” July 1990, based on the data submitted with a request for FDA approval for extended use of frozen blood.

Frozen Red Blood Cell Inventory Requirements

Frozen red blood cell inventory requirements are contained in the following plans and policies.

- ASBPO Blood Program Letter 98-7, “Revised Service Blood Product Quotas,” August 25, 1998 (the ASBPO letter), identifies specific inventory requirements for each ASWBPL and overall inventory requirements for USEUCOM and USPACOM.
- Draft Appendix 2 to Annex Q, March 2000,⁶ of USPACOM Operations Plan 5027-98, is a revised plan that identifies specific inventory requirements for the individual blood program organizations within USPACOM. If approved, the March 2000 plan will replace the current requirements outlined in USCINCPAC (U.S. Commander in Chief, U.S. Pacific Command) Instruction 6530.2J, “U.S. Pacific Command Joint Blood Program,” April 20, 1998. The revised plan contains reduced inventory requirements from the current plan based on lower casualty expectations.
- OPNAV Instruction 6530.4A, “Department of the Navy Blood Program,” October 14, 1994 (the Navy Instruction), identifies frozen red blood cell inventory requirements for Navy military treatment facilities and ships. Ship requirements were revised in Navy memorandum, “Review of Shipboard Frozen Blood Requirements,” February 26, 1997 (the Navy Memorandum). The Navy revised the inventory requirements for selected Navy installations in CONUS and one facility in USPACOM, in an October 24, 2000 memorandum, “Reorganization of the Navy Blood Program and Revised Blood Donor Center Operational Requirements” (the Navy Revision Memorandum).

⁶The blood inventory requirements in the draft appendix in Operations Plan 5027-98 have not been officially approved by the ASBPO; however, the ASBPO indicated approval is likely. Therefore, the revised lower inventory requirements stated in the Operations Plan are being used in this report.

Frozen Blood Inventory

The DoD blood program offices did not properly manage the frozen red blood cell inventory of the Blood Program. Of the 33 blood program organizations that reported frozen blood inventory, 18 did not meet their specific inventory requirements, as established by the blood program offices. The 33 blood program organizations included 2 ASWBPLs, 4 organizations in USEUCOM, 14 organizations in USPACOM, the Naval Medical Center Portsmouth, Virginia, (including 5 U.S. Atlantic Fleet ships), and the Naval Medical Center San Diego, California, (including 6 U.S. Pacific Fleet ships).⁷

The frozen red blood cell inventory includes three categories of frozen red blood cells.

- Fully tested and nonexpired units.
- Untested units, that is, units not tested for the HIV-1 p24 antigen, but appropriately labeled.
- Expired units, that is, units more than 10 years but less than 21 years old.

The blood program offices could not identify the number of frozen red blood cell units that fell into the various categories for the blood program organizations' inventory.

DoD allows using any of the three categories of blood units for contingency purposes, because FDA approved using appropriately labeled, untested units for military need, and DoD approved using blood more than 10 years but less than 21 years old for contingency use. However, we believe that DoD should strive to have frozen blood inventory composed entirely of fully tested, nonexpired red blood cell units.

Figure 1 shows the on-hand frozen blood inventory at the ASWBPLs, USEUCOM, and USPACOM compared with the requirements identified in the ASBPO Letter. Figure 2 shows the on-hand frozen blood inventory of Naval facilities compared with the requirements outlined in the Navy Instruction and the Navy Memorandums. The inventory data includes known untested and expired units.

⁷The Blood Bank Division Officers for the Naval Medical Centers at Portsmouth and San Diego also serve as the respective blood program managers for the Atlantic and Pacific Fleets.

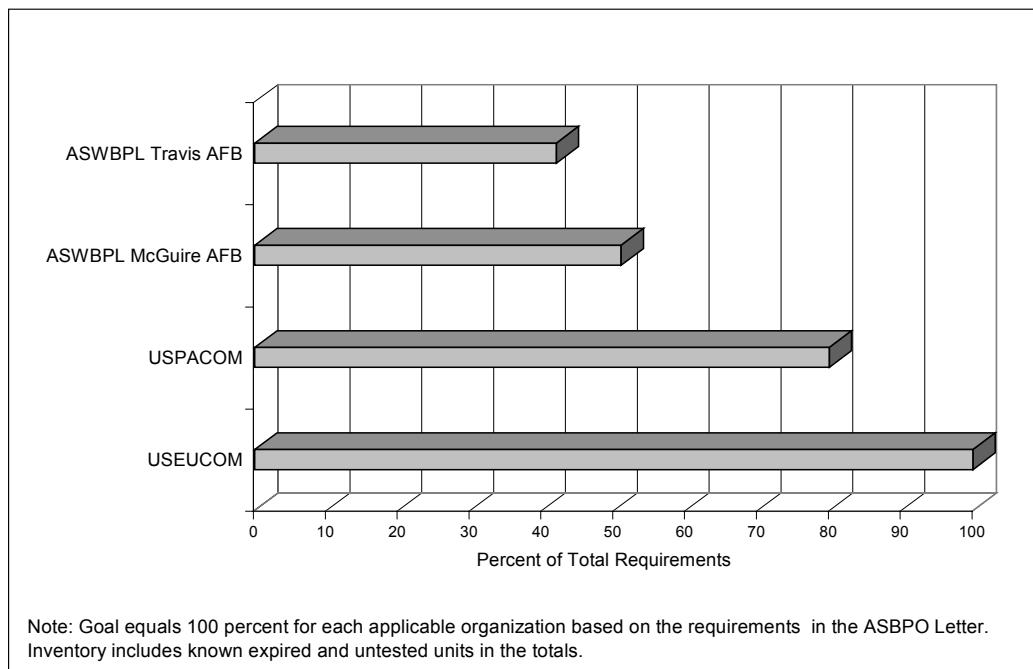


Figure 1. Frozen Blood Inventory and Requirements Based on the ASBPO Letter

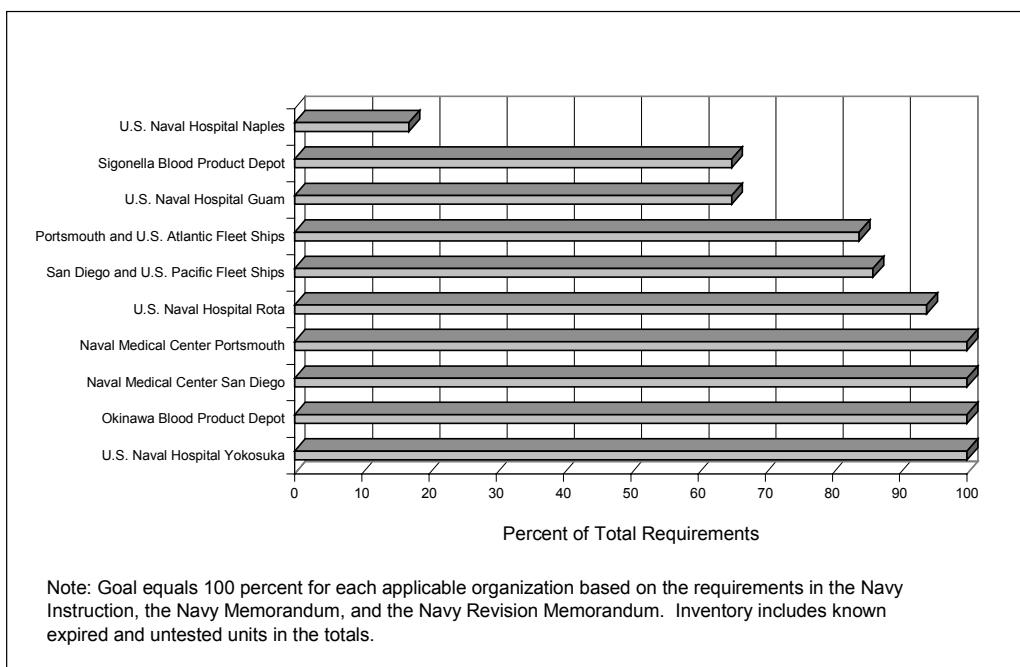


Figure 2. Navy Frozen Blood Inventory and Requirements

Armed Services Whole Blood Processing Laboratories. Inventory requirements for the ASWBPLs are identified in the ASBPO letter. The ASWBPL at McGuire Air Force Base (AFB), New Jersey, met 51 percent of the inventory requirements contained in the ASBPO letter. The ASWBPL at Travis AFB, California, met 42 percent of its inventory requirements contained in the ASBPO letter. If the known untested and expired units are removed from the inventory, the inventory rates drop to 16 percent and 32 percent, respectively.

U.S. European Command. The total frozen red blood cell inventory requirements for USEUCOM are included in the ASBPO letter. In addition, the Navy Instruction identifies requirements for the three Navy facilities. USEUCOM met the inventory requirements contained in the ASBPO letter. If the known untested or expired units are removed from the on-hand inventory, USEUCOM meets 75 percent of its inventory requirements. The rate may be less than 75 percent because untested units were reported by only one of the four USEUCOM facilities.

None of the three Navy facilities in USEUCOM met inventory requirements, as stated in the Navy Instruction. Based on total inventory, the facilities had 94 percent, 65 percent, and 17 percent of current inventory requirements. Of the three Navy facilities, two could not identify the number of untested units and one did not have expired units. If known untested and expired units are removed from the inventory, the first facility's inventory rate remains unchanged; however, the remaining two facilities inventory rate drops to 46 percent and 9 percent, respectively.

U.S. Pacific Command. The ASBPO letter identifies overall USPACOM frozen red blood cell inventory requirements. In addition, the draft USPACOM Operations Plan identifies facility-specific inventory requirements whose total requirements are less than those in the ASBPO letter. Further, for the three Navy facilities in USPACOM, requirements for two are outlined in the Navy Instruction and one in the Navy Revision Memorandum.

USPACOM has 80 percent of the ASBPO-required inventory. However, if known untested and expired units are removed from the on-hand inventory, the rate drops to 60 percent. USPACOM met the total inventory requirements in the draft Operations Plan; however, five facilities did not meet their individual requirements. If known untested and expired units are removed from the inventory, the USPACOM inventory rate drops below 100 percent of the inventory requirements in the draft Operations Plan.

Of the three Navy facilities, two met their inventory requirements. However, when the known untested and expired units were removed from the inventory, no facility met its requirements.

Naval Medical Center Portsmouth and the U.S. Atlantic Fleet Ships. The Naval Medical Center Portsmouth met its frozen red blood cell inventory requirements, as required by the Navy Revision Memorandum.⁸ However, some of the frozen red blood cell units in the Portsmouth inventory are being stored for ships in port. A total of five U.S. Atlantic Fleet ships whose blood inventory is managed by the medical center have frozen red blood cell inventory requirements per the Navy Memorandum. Of the five ships, three did not meet requirements (including the two ships in port) and two exceeded requirements. When the medical center's inventory is combined with the ship's inventory, they met 84 percent of total requirements. The number of untested units was not provided and the facility had no expired units.

Naval Medical Center San Diego and the U.S. Pacific Fleet Ships. The Naval Medical Center San Diego met its inventory requirements based on the Navy Revision Memorandum. A total of six U.S. Pacific Fleet ships whose blood inventory is managed by the medical center have frozen red blood cell inventory requirements per the Navy Memorandum. Of the six ships, four did not meet requirements and two exceeded requirements. When the medical center's inventory is combined with the ship's inventory, they met 86 percent of total requirements. If the known untested or expired units are removed from the inventory, the rate drops to 33 percent.

The inadequate management of the frozen red blood cell inventory occurred because DoD did not issue clear policy that standardized identification, use, and disposition of the frozen red blood cell inventory. In addition, DoD did not develop a written plan for replacing the untested and rotating the expired or expiring frozen red blood cell units. Although the FDA approved untested units for military need and DoD allowed expired units for contingencies, DoD needs to work toward maintaining a frozen blood inventory composed of fully tested, nonexpired red blood cell units.

Inventory Identification and Disposition

The ASBPO did not issue policy that clearly describes the categories for frozen blood inventory or explains the use and disposition of expired and HIV-1 p24 antigen untested units currently in storage. Without clear policy, the ASBPO and the Military Departments were unable to properly account for the frozen blood inventory by type of unit for each blood program organization.

Blood Unit Status Descriptions. The ASBPO did not issue clear policy that describes the status of the blood units. The descriptions used to identify the status of the frozen red blood cell units in the inventory records varied among frozen blood storage facilities. Of the organizations that provided unit status descriptions for the fully tested, nonexpired units, three organizations described the units as "available," while six organizations described those units as

⁸After the draft report was issued on September 1, 2000, the Navy issued a memorandum revising the inventory requirements for its CONUS and USPACOM facilities. Prior to issuance of the Navy Revision Memorandum, the Naval Medical Centers in Portsmouth and San Diego did not meet their inventory requirements, as stated in the draft report.

“good.” Of the seven organizations that had HIV-1 p24 antigen untested units on hand and reported a unit status description, one categorized the units as “training” units, one as “quarantined,” two as “good,” and three used both “training” and “good.” Of the six organizations that had expired units on hand and reported a unit status description, two categorized the units as “training” units, two as “quarantined,” and two as “expired.” While expired blood inventory is known because all blood program organizations provided an expiration schedule based on the FDA-approved 10-year shelf life, the number of HIV-1 p24 antigen untested blood units is not known because only 42 percent of the organizations identified the untested units.

When asked for information regarding the frozen blood in storage, the ASBPO stated that “quarantined” units should be considered “training” units, but did not specify whether the unit status description should be “training” or “quarantined.” Policy is needed that clearly describes the various blood unit statuses to make the data on inventory schedules more consistent. In addition, the “Blood Bank Operational Report”⁹ used to report inventory information should be updated so that the number of units in each status category is reported.

Blood Unit Use and Disposition. The ASBPO did not issue clear guidance regarding the use and disposition of untested and expired units of blood. A July 10, 1996, memorandum from the Assistant Secretary of Defense (Health Affairs) outlines the disposition of untested units, but the memorandum does not clearly state how the units are to be used. As a result, the blood storage facilities will use or dispose of similar units differently. Most storage facilities visited have continued to maintain expired units in the event extension approval is granted by the FDA or the units are needed for a major theater war. However, because no official policy concerning the disposition of expired units has been issued, one facility is destroying its expired units. For the untested units, two storage facilities stated that untested units would be used for training purposes only, one would quarantine the units, and one indicated that they would deglycerolize and transfuse untested units in an emergency situation.

When we asked for additional clarifying information, the ASBPO provided us with a statement regarding the use of the untested units. They indicated that although fully tested frozen units are to be used first, the HIV-1 p24 antigen untested units can be used during emergencies until additional fully tested units are available. Additionally, if the stock of fully tested and untested units is exhausted and other quarantined units are available, the quarantined units may be used at the discretion of the command surgeon and the JBPO. However, the ASBPO statement is not official policy for the storage facilities.

The ASBPO stated that no policy outlining identification, use, and disposition of blood units that are both untested and expired has been issued. They indicated that each facility may be identifying and storing the units differently. Such lack of guidance and likely variation in storing blood units complicates the problem because it is no longer clear which units of blood, if any, should be used once

⁹The Blood Bank Operational Report, DD Form 2555, is a quarterly report identifying blood inventory and operations data. The report is prepared by the blood program organizations, consolidated by the SBPOs, and forwarded to the ASBPO.

fully tested, nonexpired blood units are exhausted. A policy is needed that clearly describes the use and disposition of the various blood units and the priority for using the units in the event of a contingency.

Increased Testing. We realize that the readiness of the Blood Program has been impacted by an ever-increasing regulatory environment under which the ASBPO and the SBPOs have been required to operate. In the past 10 years, the FDA has added new tests for the blood, limited possible blood donor sources, and established new guidelines for quality assurance and training. One such test, the Nucleic Acid Test, is in the investigation stage and expected to become a mandatory requirement. The new test further reduces the time between exposure to the Hepatitis C virus or HIV and a positive test result.

Each change in blood testing requirements approved by the FDA has a significant impact on the frozen blood program. While freshly collected blood may be tested without difficulty, testing frozen blood is more difficult. Once an additional test is required, all the frozen blood in inventory should be tested. Because some units do not have cryovials, tests may not be possible. To manage a likely increase in testing requirements by the FDA, the ASBPO, in coordination with the SBPOs, needs to develop a plan for implementing new tests in the future as they are required on the current frozen blood inventory. In addition, the plan should address the requirements for future frozen blood collections to ensure adequate quantities of blood samples are available should new tests be required after the unit is frozen.

Stock Replacement and Rotation

The DoD has not established a written plan to replace the expiring frozen blood supply. The ASBPO did not require replacement of expired or expiring frozen red blood cell inventory or implement a stock rotation program to use expiring blood products during peacetime.

Stock Replacement. Based on the current FDA-approved shelf life and the inventory data provided by ASBPO and the organizations visited, without replacement 48 percent of the current frozen blood inventory will expire by the end of calendar year 2001 and 71 percent by the end of calendar year 2002. The expired frozen blood inventory can only be used in the event of a contingency. Although the ASBPO has not required the Military Departments to ship frozen red blood cells to the ASWBPLs to replace the expiring inventory, the Navy had a requirement for four of its blood donor centers (BDCs) in CONUS to freeze and ship red blood cell units to the ASWBPLs. In a September 2000 message, the Navy reduced the number of facilities required to freeze and ship frozen red blood cells to two facilities. However, only one facility shipped units in 1998 and 1999, and that facility has shipped less than the Navy requirement. In addition, neither of the two facilities currently required to ship units have shipped any units since the issuance of the message.

The DoD has submitted three separate requests to the FDA for approval to extend the frozen shelf life of the product, the last request asking for an extension to 17 years. Approval has not yet been granted by the FDA because of concerns with the recovery rate of the red blood cells after thawing and deglycerolization.

Blood Program management has delayed freezing new red blood cell units pending FDA approval of several initiatives that will improve the quality and use of frozen red blood cells. Additional information concerning the FDA requests and future initiatives regarding the frozen blood program, such as use of an automated, functionally closed system, is in Appendix E.

Stock Rotation. A stock rotation program would require peacetime use of the frozen blood. While Joint Publication 4.02-1 allows a 72-hour shelf life after thawing and deglycerolizing for wartime purposes, the FDA has approved only a 24-hour post-thaw shelf life, which would apply during peacetime. The short shelf life hinders the use of the frozen red blood cells in peacetime because blood is often cross matched the day prior to a surgery and, depending on need, may not be used for 1 to 2 days after surgery, far exceeding the 24-hour shelf life. If DoD receives FDA approval of the proposed initiatives for freezing and deglycerolizing red blood cells, the post-thaw shelf life will increase to 14 days, improving the feasibility of using frozen blood in peacetime. However, FDA approval and DoD implementation of the new technology will take time.

The DoD continues to support the frozen blood program as one of the methods to meet future blood needs for wartime. The ASBPO stated that frozen blood is one aspect of a complete blood program. If the frozen blood program is to stay viable, DoD must develop a plan to eventually have a frozen blood inventory composed entirely of fully tested, nonexpired units. That replacement plan could include rotating the stock and using the frozen products during peacetime. The DoD needs to determine if using frozen products in peacetime is feasible, and if so, the Assistant Secretary of Defense (Health Affairs), in coordination with the Surgeons General, should develop an implementation plan.

The ASBPO estimates the cost to replace blood that has exceeded the 10-year frozen shelf life will be approximately \$7.6 million. The estimate does not include replacing the blood stored at the ASWBPLs, the BDCs in CONUS, or on the ships. The Military Departments have not budgeted to replace the untested or expiring inventory. If the frozen blood program is to continue, the Military Department Surgeons General must include in future budgets the cost for replacing the untested and expired frozen blood inventory.

Inventory Reporting and Accountability

DoD did not have accurate frozen red blood cell inventory reporting and accountability which could impact major theater war operations. The DoD does not know the number of units that are untested, expired, or both untested and expired. The problem may multiply over time.

In addition, delaying replacement of untested and expired frozen red blood cells will continue to force the DoD to rely on untested, expired blood to meet contingency inventory requirements. It will take time to obtain FDA approval for extending the shelf life of frozen red blood cells, freezing of platelets, and

allowing DoD use of the new automated, functionally closed systems. If a major theater war should occur in the next few years, unless DoD establishes a frozen blood replacement strategy, the initial blood supply will be composed primarily of untested, expired, or both expired and untested red blood cells.

Management Comment on the Finding and Audit Response

Armed Services Blood Program Office Comments. The ASBPO partially concurred with the finding. They concurred that additional frozen red blood cell inventory reporting is needed by the unified commands, the ASWBPLs, the Navy ships, and the blood product depots, including reconciling unit inventory with cryovial inventory. However, they did not concur with the statement that the inventory was not adequate to meet contingency requirements. Based on the April 8, 1996, FDA letter, the ASBPO considers untested units that are appropriately labeled suitable to meet military needs. In addition, for contingency purposes, the ASBPO plans to use frozen red blood cell units that are up to 21 years old as approved by the Defense Medical Standardization Board. The ASBPO agreed that the policy regarding the use of expired blood is not clear, and they will issue a policy letter and update the Technical Manual to correct the problem. In addition, the ASBPO plans to issue guidance that outlines the new inventory requirements after revised unified command requirements are finalized. The ASBPO agrees that the current inventory will eventually have to be replaced. However, the ASBPO stated that replacement of the inventory is not practical until they receive FDA approval of new blood freezing technology that offers enhanced efficiency and utilization.

The ASBPO partially concurred with our finding statement concerning the clarity of the policy regarding standard identification, use, and disposition of inventory. They acknowledged that decisions were not always well documented, communicated, and followed up. They also stated guidance will be issued regarding quarantined blood products. Regarding plans for replacement of untested and expired blood, the ASBPO stated a plan has not been formalized because the focus has been on improving both the product and the process for producing frozen red blood cells. Before any replacement plan is initiated, the ASBPO will formulate a plan to validate the inventory, compare it with the inventory requirements in the operations plans, and then issue guidance to the Services and the unified commands.

The ASBPO believed the impediment to the successful management of the Blood Program has been insufficient staffing at the ASBPO, the SBPOs, and the JBPOs. As a result, the focus of meeting the ever-increasing FDA regulations to maintain peacetime requirements, combined with insufficient staffing in the unified commands and the Military Departments, has impacted the ability to oversee the readiness elements of the Blood Program.

Audit Response. The ASBPO concurred with the key issues in the finding. Regarding the partial concurrence on the availability of blood for contingency purposes, we revised the finding and supporting data to accommodate FDA approval of the appropriately labeled, untested units for military need. We also revised the report to allow for contingency purposes frozen red blood cells that are more than 10 years but less than 21 years old. We support the ASBPO

effort to eventually replace the frozen red blood cell inventory when the new, improved equipment is approved by the FDA. We also agree that the program offices are not adequately staffed. Sufficient staffing is critical in light of the ever-increasing FDA requirements, the constant changes in technology, and the increased need for oversight by the SBPOs and the JBPOS to ensure readiness needs, as well as peacetime needs, are being met.

Navy Comments on Discussion of Navy Inventory. The Navy requested clarification regarding the discussion of frozen blood requirements at Navy facilities. The Navy stated that the Navy Instruction does not expand on the ASBPO and unified command requirements, instead the Instruction supports them. They further stated that the ASBPO and unified command requirements supercede the Navy Instruction and that the Navy Instruction is no longer valid and is under revision. The Navy indicated that their facilities in USEUCOM and USPACOM meet the requirements based on the ASBPO Blood Product Letter and the revised unified command operations plans. In addition, in an October 24, 2000, memorandum, the Navy revised the frozen blood requirements for CONUS facilities. Regarding ship inventory, the Navy stated that some frozen red blood cell units are designated for the ships and reported in the ships' inventory, although not on board the ship. In conclusion, the Navy declared that adequate frozen units exist to meet full Navy mobilization requirements if units located at Navy CONUS and overseas facilities and at the ASWBPLs are considered.

Audit Response. The Navy revised its inventory requirements on October 24, 2000, after the draft report was issued. The draft report identified several Navy facilities that failed to meet inventory requirements in effect at the time the draft report was issued. We modified the audit report to reflect current inventory requirements. In addition, we deleted the statement that the Navy Instruction expanded the ASBPO and unified command requirements. We also revised the report to include ships-in-port inventory with the inventory of the facility storing the blood, resulting in the ships not meeting their inventory requirements. However, we did not delete reference to the Navy Instruction for two reasons. First, the Navy Instruction has never been rescinded. We have no documentation other than the recent comments to the draft audit report that indicate the Instruction is no longer valid. If the Instruction is not valid, the Navy should cancel the Instruction. Second, neither the ASBPO letter nor the unified command operations plans state that their requirements supercede the Navy Instruction. The Navy has the authority to have additional requirements other than those in the ASBPO letter or the unified command operations plans. We consider the Navy Instruction and Memorandums as support for their additional needs. In addition, neither the USEUCOM or USPACOM operations plans address ship requirements, and those ships may have to be supported by Navy facilities outside CONUS. However, even with the revised requirements, the Navy did not fully meet its inventory requirements.

USPACOM Comments on Meeting Inventory Requirements. USPACOM explained that the finding was based on operations plans currently under revision and that inventory levels are adequate when the revised requirements are used.

Audit Response. We acknowledge that the operations plans are under revision, which is included on pages 5 and 8 of this report. However, USPACOM may have to redistribute inventory to meet facility-specific requirements.

Recommendations, Management Comments, and Audit Response

A.1. We recommend that the Director, Armed Services Blood Program Office, in coordination with the Surgeons General of the Military Departments and the Joint Staff:

a. Issue policy that:

- (1) clearly defines the various categories of blood unit status, such as available, training, quarantined, untested, or expired;
- (2) requires all categories of blood unit status be reported on the Blood Bank Operational Report; and
- (3) clearly identifies the use and disposition of each unit, including those with multiple statuses.

Armed Services Blood Program Office Comments. The ASBPO concurred and will issue a policy letter that specifies the terms to be used and define each term. Additionally, they will specify the proper use and disposition of units and the priority of use of units during contingencies. Further, the ASBPO will determine procedures for verifying inventory categories and incorporate inventory control management in a formal management plan and update the Blood Bank Operational Report to more accurately reflect the status of the frozen red blood cell inventory. The ASBPO stated that corrective actions would be accomplished during March through August 2001.

Navy Comments. The Navy stated that clarification was needed regarding guidance on the use and disposition of non-HIV antigen tested units. They reported that the ASBPO and the Navy issued policy addressing that issue in 1996.

Audit Response. While some policy had been issued, the current guidance did not adequately explain all the categories of frozen red blood cell units. We requested use and disposition guidance be issued that addresses all of the frozen units, not simply the untested ones. The guidance should clearly define the different categories and clearly identify the use and disposition of each unit, whether available, training, quarantined, untested, or expired. In addition, per the ASBPO, the 1996 letter issued by the Assistant Secretary of Defense (Health Affairs) referenced by the Navy is no longer valid and is being rescinded by the ASBPO.

b. Develop a plan of action for implementing new tests as the tests are required on frozen blood units in the future. The plan should address additional tests on current frozen inventory and include requirements for testing future blood collections to ensure adequate quantities of collected blood is available when the new tests are required.

Armed Services Blood Program Office Comments. The ASBPO concurred with the recommendation. They will issue a formal plan; however, they believe the current policy to have cryovials for each frozen red blood cell unit allows for future testing. They will obtain guidance from the FDA if new tests are required and cryovials are not available or suitable.

c. Establish management controls to ensure frozen blood inventory requirements are met at all blood storage facilities with fully tested, nonexpired frozen blood units.

Armed Services Blood Program Office Comments. The ASBPO partially concurred with the recommendation, stating that fully tested, or appropriately labeled, nonexpired (21 year old) units, meet inventory requirements. They will collect information on the number of units retained for contingency purposes only, that is, not fully tested or more than 10 years old. The units will be appropriately labeled or quarantined for contingency use. After FDA approval and Service acquisition of new blood freezing equipment, the ASBPO will publish replacement inventory requirements and task the Services to meet them. In addition, if approval is received from the FDA to use frozen red blood cells beyond the current 10-year approval period, the expired units will be moved from quarantined inventory to available inventory.

Audit Response. The ASBPO comments were fully responsive. However, we continue to believe the ultimate goal should be to have the inventory supplied with fully tested, nonexpired frozen red blood cell units. We acknowledge that for contingency purposes, appropriately labeled, untested units, and units more than 10 years but less than 21 years, are allowed.

A.2. We recommend that the Assistant Secretary of Defense (Health Affairs), in coordination with the Surgeons General of the Military Departments, study the feasibility of using frozen blood in peacetime and, if feasible, develop an implementation plan.

Armed Services Blood Program Office Comments. The ASBPO concurred with the recommendation. However, they stated that the use of the frozen blood under the current 24-hour post-thaw limitation is not workable. Once DoD has a licensed 14-day post-thaw product, the ASBPO will coordinate with the Services to study the feasibility of using the product at busier transfusion services.

Navy Comments. The Navy concurred with comments. The Navy supports use of frozen blood in peacetime. However, the facilities with frozen units are not located near military treatment facilities and have to be shipped. The Navy stated that full implementation could be costly.

Air Force Comments. The Air Force concurred and agreed to coordinate with the Assistant Secretary of Defense (Health Affairs), the Army, and the Navy to study the feasibility of using frozen blood during peacetime.

A.3. We recommend that the Surgeons General of the Military Departments include funding in future budgets for replacing untested and expired frozen red blood cell units.

Army Comments. The Army concurred and will submit a funding request after a replacement plan is developed by ASBPO.

Navy Comments. The Navy concurred with comments. The Navy agreed that funding must be provided in future budgets for replacing frozen blood inventory. However, they believe a replacement plan should be designed to only replace units that exceed the 21-year dating. In addition, replacement should not be accomplished until equipment is available that will ensure a 14-day post-thaw shelf life, and funding should include continued support for the new equipment research.

Air Force Comments. The Air Force concurred and agreed to request funding for replacement of frozen red blood cell units once the ASBPO establishes a plan for replacing the units and provides cost estimates.

Audit Response. The Army and Air Force comments are fully responsive. The Navy comments are partially responsive. The Navy agreed that funding needs to be provided for replacing expired inventory but did not address replacement of untested inventory. We request that the Navy provide additional comments in response to the final report.

B. Mobilization Planning and Training

DoD needs to improve mobilization planning and training for the Blood Program. Two of three Military Department blood program offices did not prepare sufficient mobilization planning documents. Nine of the 15 blood program organizations visited did not have written, approved mobilization plans¹⁰ that would clearly identify actions needed by the organizations in the event of a contingency. In addition, 13 of the 15 blood program organizations visited have mobility missions and 6 of those had training problems. Improvements are needed because the Navy and Air Force did not require mobilization planning documents from their blood program offices. In addition, written, organization-specific mobilization plans were not required for Army blood product depots and Navy blood program organizations. Further, the Military Departments did not ensure personnel assigned to augment or backfill blood program organizations were adequately trained to handle their mobility mission. As a result, the blood program organizations may not be able to properly activate in the event of a mobilization.

Mobilization Requirements

Planning Requirements. For the blood program offices, the Army, Air Force, and unified commands have mobilization plans that include the blood program office. The Navy blood program office did not have a mobilization plan.

- “U.S. Army Medical Command Mobilization Plan,” November 24, 1999, states the Army Blood Program Office is responsible for the Army Blood Program and the office will be required to identify mobilization sources and blood quotas. The Army Blood Program Office has published memoranda and charts that identify the mobilization sources and blood quotas.
- The Air Force “War Mobilization Plan,” undated, outlines the role of the Air Force in supporting the Blood Program, including the role of the major command surgeons, the ASWBPLs, the BDCs, the Blood Transshipment Centers (BTCs), and the Transportable BTCs.
- USEUCOM Appendix 2 to Annex Q, undated, of the unified command’s Operations Plan, provides the concept of operations, tasks, and guidance for distributing blood to support USEUCOM. The plan appendix is supplemented with USEUCOM Directive 67-4, “USEUCOM Joint Blood Program,” August 22, 1999, which provides guidance and responsibilities for the commands and organizations within the USEUCOM area of responsibility.

¹⁰For this report, mobilization plans include contingency or operations plans.

-
- Draft Appendix 2 to Annex Q, March 2000, of USPACOM Operations Plan 5027-98, provides guidance for full operational oversight and management of the USPACOM joint blood program. The plan appendix is supplemented with USCINCPAC Instruction 6530.2J, that assigns roles, responsibilities, and authority to the Joint Blood Program organizations and describes the coordination of the unified, sub-unified, and component command blood programs.

In addition, the Army and the Air Force require mobilization plans for their blood organizations; the Navy does not. Army Medical Command Regulation 500-5-5, “U.S. Army Medical Command Commanders’ and Medical Mobilization Planners’ Handbook,” June 14, 2000, requires BDCs to prepare an appendix to the medical treatment facility plan that provide guidance for executing the mobilization blood program mission. Air Force Instruction 41-106, “Medical Readiness Planning and Training,” March 1, 1999, requires Air Force organizations and medical facilities to develop medical contingency response or concept of operations plans.

Training Requirements. The Army Technical Manual 8-227-11/NAVMED P-5123/Air Force Instruction 44-118, “Operational Procedures for the Armed Services Blood Program Elements,” September 1, 1995 (the Joint Publication), establishes general training guidance for the ASWBPLs, BDCs, BTCs, and blood supply units. It states that blood program organizations are required to train at a minimum on an annual basis. The Air Force has expanded training requirements to specify more detailed training of their contingency personnel.

Mobilization Planning and Training Readiness

DoD needs to improve mobilization planning and training for the Blood Program. Specifically, the blood program organizations did not consistently prepare mobilization plans or ensure personnel assigned to augment or backfill blood program organizations were trained.

Planning Readiness. Mobilization plans were not consistently prepared. We visited 6 blood program offices and 15 blood program organizations. Of the program offices visited, only the unified commands need to prepare formal mobilization plans and both unified commands visited had comprehensive plans. The ASBPO does not need to prepare a mobilization plan. Although the SBPOs do not need to prepare formal mobilization plans, they should be required to complete mobilization planning documents that include, at a minimum, blood quotas and mobilization sources. While all three SBPOs established blood quotas, only the Army had written reports that identified mobilization sources.

Mobilization planning by the 15 blood program organizations visited was not sufficient. Only six blood program organizations prepared formal plans—four had mobilization plans and two used published concept of operations guidelines. The organizations with plans were the ASWBPL at McGuire AFB, three BTCs, and two transportable BTCs. The remaining nine blood program organizations did not have any type of written mobilization plans. Those included six BDCs, two blood product depots, and the ASWBPL at Travis AFB. While required by the Army and Air Force, none of the BDCs visited had published plans on hand.

The following table summarizes the mobilization planning by the blood program activities.

Mobilization Plans			
	Activity	Number of Activities Visited	Number of Activities with a Plan
Blood Program Offices	SBPO	3	1
	JBPO	2	2
	ASWBPL	2	1
	BDC	6	0
	BPD ¹	2	0
	BTC	3	3
	TBTC ²	2	2

¹Blood Product Depot

²Transportable Blood Transshipment Center

Of the six blood program organizations that published plans, all were Air Force organizations. However, only one had a complete plan—the ASWBPL at McGuire AFB. The mobilization plans prepared by the three BTCs included most of the required information; however, each plan lacked specifics required by the Air Force policy. The two transportable BTCs relied on the Air Force “Air Combat Command Concept of Operations for the Transportable Blood Transshipment Centers,” February 12, 1999, which outlines the roles and responsibilities of the transportable BTCs. While that document contains detailed instructions regarding setting up and operating a transportable BTC, it does not include organization-specific requirements, such as lines of communication and transportation support.

Training Readiness. The training of personnel from blood program organizations with mobility missions was not always adequate. Of the 15 blood program organizations we visited, 13 had direct mobility missions and 6 of those had organization-level training problems. The training problems involved uncertainty about the level of training for personnel who will augment or backfill the blood program organization. In addition, joint- or unified command-level training exercises only occurred in one unified command.

Organizational Readiness

The mobilization planning problems occurred because the blood program organizations did not consistently prepare mobilization plans. The training problems occurred because the Military Departments did not ensure personnel assigned to augment or backfill units were trained. While the Air Force has a mobilization plan, the plan did not require the Air Force SBPO to prepare mobilization planning documents. The Navy SBPO also was not required to prepare mobilization planning documents. Further, the Army did not require mobilization plans from its blood product depots and the Navy did not require plans from its blood program organizations. In addition, none of the Military Departments ensured augmentee or backfill personnel were trained to their mobility mission.

Organizational Planning. The Military Departments did not consistently require mobilization plans. Each blood program organization has a role in supporting delivery of blood to military units in the event of a contingency or war. Those roles are outlined in DoD, Military Department, and unified command policies. However, the policies are in general terms and are not specific to an individual blood program organization.

The Navy and the Air Force need to require their SBPOs to prepare mobilization planning documents. At a minimum, the Navy and Air Force SBPOs should include in their mobilization planning documents the requirement to establish blood quotas and identify mobilization sources, as is currently required by the Army SBPO. While the Navy and the Air Force established blood quotas for their blood program organizations, they could not readily identify mobilization sources.

The blood program organizations should have mobilization plans that supplement published policies. The mobilization plans would identify how the individual organization or unit will operate during a mobilization, including clearly defined roles and responsibilities, contacts and lines of communication, training requirements, transportation support, and implementing guidance for the individual members of the organization or unit. All blood program organizations with a contingency or mobility mission should have an organization-level mobilization plan or an annex to a medical treatment facility or installation plan.

Organizational Training. The Military Departments did not ensure that personnel assigned to augment or backfill blood program organizations were trained to handle their mobility mission. A key element of readiness is having staff trained to perform the mobility mission. Training contingency personnel includes two types of training. First, individual organizations need to complete stand-alone, organization-level training so they can learn how to work as a team and individuals within the organization can better understand their roles. Second, organizations need to train in exercises so they experience interacting with other organizations in their area of responsibility.

Organization-Level Training. Organization-level training was not adequate at 6 of the 13 blood program organizations visited that have mobility missions. There were organization-level training issues at both ASWBPLs, two BDCs, and two BTCs. There was uncertainty about the level of training received by personnel that will augment or backfill the blood program organization. To ensure familiarity with operational procedures, personnel are required by the Joint Publication to train annually for their mobility mission. Ideally, training would occur at the site the personnel will augment; however, that is not always practical. We believe that for reserve units the annual training should be at their mobility site or a similar one.

For both ASWBPLs, none of the personnel assigned to augment the unit has ever trained on site. The DoD Instruction 6480.4 states that Military Departments should specify the personnel who will staff contingency positions at the ASWBPLs. While the Army and Navy SBPOs could identify their augmentees to the ASWBPLs, the Air Force SBPO could not. Without knowing the mobilization staffing sources, it is difficult to adequately plan for training. While it may not be a problem with active duty units that may be trained in the technical functions performed at the ASWBPLs as part of their primary duties, this is not true for reservists or active duty personnel whose primary mission is different than their mobility mission. For example, one ASWBPL reported that when reserve units augmented its unit during Desert Shield/Storm, the reservists were not trained. The Army is starting to correct the problem by sending one of its two reserve units assigned to support the ASWBPLs for on-site training in FY 2001. The Air Force does not have similar plans with its reserve units designated to augment the ASWBPLs. The Navy does not augment the ASWBPLs with reserve personnel, but active duty personnel designated to augment the ASWBPLs that have mobility missions different than their primary mission should train on site.

The problems at the two BDCs are also related to concerns about the training of augmentee and backfill personnel. In the event of a contingency, the primary staff for the BDCs would deploy to augment other units, which would leave the BDCs extremely understaffed. Reserve units designated to augment or backfill the BDC have not trained at the unit. The reserve units should perform annual training at their assigned mobility site or a similar one to ensure they can perform their mobility functions.

Two BTCs could also have problems if a contingency occurs. At one BTC the primary personnel had an alternate mobility mission and were to only staff the BTC until backfill personnel arrive. The contingency units designated to backfill the initial staff were not known and had never trained on site. At the other BTC, the primary staff was not adequately trained. While the primary staff had training sessions, they have never processed blood product shipments through the equipment. In addition, the team chief at the unit did not maintain a complete training binder, lesson plans, or after-action reports as required by Air Force policy.

Unified Command-Level Exercise Training. Only the USPACOM JBPO required its blood program organizations to participate in unified command-level training exercises. During a recent USPACOM field training exercise, half of a pallet of blood was shipped from the ASWBPL at

Travis AFB through the BTCs and blood product depots to determine if each organization performed its mobility mission correctly. During the exercise each organization performed its mobility roles to test the blood product processing procedures by the local contingency staff. The exercise after-action report included lessons learned for transportation planning and re-icing requirements. Similar training did not occur within CONUS or at USEUCOM.

Meeting the Mobility Mission

Without adequate planning and training, the DoD cannot ensure blood program organizations with mobility missions will be able to properly activate in the event of a contingency. The blood program organization should have published approved plans that outline their specific roles and responsibilities, including the lines of communication and expected support systems in the event of a contingency. In addition, the blood program organizations must be adequately trained in their mobility mission to quickly and correctly activate the unit, including personnel assigned to augment or backfill the organization.

Management Comment on the Finding

Armed Services Blood Program Office Comments. The ASBPO concurred with the finding. As a part of the ASBPO Management Plan, they will require annual assessments from the Services and the unified commands, including a review of mobilization plans, status of training, review of equipment and supplies, and frequency of exercises.

Recommendations, Management Comments, and Audit Response

Revised Recommendation. As a result of management comments, we revised draft Recommendation B.2. to clarify the requirement for mobilization planning documents.

B.1. We recommend the Surgeons General of the Military Departments establish management controls to ensure that:

- a. All blood program organizations with contingency or mobility missions
 - (1) prepare written mobilization plans,
 - (2) identify augmentation or backfill sources, and
 - (3) adequately train their staff.

Armed Services Blood Program Office Comments. The ASBPO concurred with the recommendation.

Army Comments. The Army concurred stating they have actively worked on realignment, missioning, and training of Reserve components supporting the blood program. Additionally, an organization mobilization assessment tool was submitted to individual BDCs to aid in the evaluation of an organization's readiness posture and mobilization mission requirements.

Navy Comments. The Navy partially concurred with the recommendation. The Navy requirements to identify overall staffing sources are covered in the Bureau of Medicine and Surgery Instruction 6440.5B, "Medical Augmentation Program." The policy was revised in May 2000 to include component unit identification codes for mobilization platforms, including BDCs. The Navy acknowledged that personnel have not been consistently and officially identified and trained to operate and augment BDCs and ASWBPLs. However, action is being taken to correct the problem. The Navy plans to issue a new BDC Mobilization Instruction that will require each facility to develop a mobilization plan, identify responsibilities and how the BDC will operate during mobilization, and staffing and augmentation team training requirements.

Air Force Comments. The Air Force concurred and stated that an Air Force instruction requires contingency plans for medical elements. The Air Force Inspection Agency is tasked by that Air Force instruction to ensure blood program organizations prepare contingency or mobility plans, identify backfill resources, and evaluate training. The Surgeon General will task the Air Force Inspection Agency to provide the findings from its biennial evaluations of blood program organizations to the Medical Readiness Office, Office of the Surgeon General. In addition, the Air Force stated that augmentation resources are further identified in Air Force Medical Resource Letters that are updated semiannually.

Audit Response. The Army comments are partially responsive. The Army needs to incorporate an oversight capability to ensure that the BDCs complete the mobilization assessment. In addition, the Army needs to ensure blood product depots are also evaluated on their readiness posture. We request that in response to the final report, the Army provide specific details on overseeing the mobilization planning by the Army blood program organizations.

The Navy comments are partially responsive. The proposed mobilization instruction addresses mobilization planning and training for BDCs. However, the instruction does not address mobilization planning for the blood product depots. Additional comments are needed to explain how and when mobilization planning and training will be accomplished at the other facilities.

b. All active duty personnel assigned to augment or backfill blood program organizations are trained in their mobility mission.

Armed Services Blood Program Office Comments. The ASBPO concurred with the recommendation.

Army Comments. The Army concurred and indicated that they have provided BDCs with an organizational assessment tool to evaluate their readiness posture.

Air Force Comments. The Air Force concurred and stated the Air Force Inspection Agency will determine if the requirement is being met and will be tasked to report the findings to the Medical Readiness Office, Office of the Surgeon General.

Audit Response. The Army comments are partially responsive. The Army did not provide details on how they will ensure active duty personnel assigned to blood program organizations are properly trained in their mobility mission. In response to the final report, we request the Army provide details on the oversight method they will use to ensure active duty personnel assigned to mobility missions in blood program organizations are adequately trained.

The Navy did not comment on the recommendation. We request that the Navy provide comments on the final report.

c. Reserve units assigned to augment or backfill blood program organizations are trained in their mobility mission and, whenever possible, train at their mobility site or one similar.

Army Comments. The Army concurred and indicated that they are working on training reserve components supporting the blood program.

Air Force Comments. The Air Force concurred and stated the Air Force Inspection Agency will conduct a biennial review of the training at the reserve units and determine if the requirement is being met. The findings and results of the review will be forwarded to the Medical Readiness Office, Office of the Surgeon General. In addition, at the next Air Force Annual Tour Allocation Conference, the Surgeon General will recommend that reserve unit train at the mobility site.

Audit Response. The Army comments are partially responsive. The Army did not provide the controls that will be used to ensure the reserve components are adequately trained. In response to the final report, we request the Army provide the oversight that is planned to ensure the training is accomplished.

The Navy did not comment on the recommendation. We request that the Navy provide comments on the final report.

B.2. We recommend the Surgeons General of the Navy and Air Force issue policy that requires its blood program office to prepare mobilization planning documents that include, at a minimum, blood quotas and mobilization sources.

Armed Services Blood Program Office Comments. The ASBPO partially concurred with the recommendation. They stated that because the SBPOs establish blood quotas, clarification is needed regarding the recommendation. The ASBPO agreed that blood quotas and mobilization sources should be included in the Service mobilization plans.

Navy Comments. The Navy partially concurred with the recommendation. The Navy requested clarification regarding establishment of quotas and preparation of mobilization planning documents, stating that the Bureau of Medicine and Surgery does require identification of mobilization staffing sources and does establish blood quotas.

Air Force Comments. The Air Force partially concurred with the recommendation. It recommended that we delete the requirement for establishing blood quotas. The Air Force also stated that currently no mobilization sources in the Air Force Blood Program Office exist and positions are being advertised.

Audit Response. The Navy comments are partially responsive. The recommendation was modified to more clearly explain the intent of the recommendation. The Navy indicated that they are required to identify mobilization staffing sources; however, we did not find that the SBPO was officially tasked to maintain mobilization sources supporting all of the blood program organizations. In addition, while the Navy SBPO did establish blood quotas, the requirement to do so was not officially required. We request that, in response to the final report, the Navy indicate how and when they will formalize a requirement to prepare mobilization planning documents that include blood quotas and mobilization sources.

The Air Force comments are partially responsive. The recommendation was modified to clarify our intent to formalize the requirement to establish blood quotas and identify mobilization sources to ensure it is consistently done in the future. Regarding the comment on augmentation of staff to the Air Force SBPO, our recommendation was to ensure the Air Force mobilization planning documents included mobilization sources at all blood program organizations, not merely the program office. We request the Air Force provide additional clarification in response to the final report.

B.3. We recommend that the Director, Joint Staff, in coordination with the unified commands and the Military Departments, incorporate blood program distribution and processing into joint- and unified command-level training exercises.

Armed Services Blood Program Office Comments. The ASBPO concurred and indicated they are working with the Joint Staff Logistics Directorate to incorporate “blood play” into joint exercises and will continue to do so. However, the ASBPO acknowledged that the unified commands and the JBPOs also need to insert the blood play into the exercises.

Joint Staff Comments. The Joint Staff comments include a statement from the JBPO within the U.S. Joint Forces Command concerning completed training. Specifically, the Joint Staff statement identified training for area JBPOs and an exercise held in June 2000.

Audit Response. The Joint Staff comments did not address the recommendation. The Joint Staff did not indicate how they will ensure blood program organizations are included in joint- and unified command-level exercises. In the past, blood training was planned but at the last minute removed from the training. The Joint Staff needs to address how it will prevent removal of blood program related training in the future. The statement from the JBPO within the U.S. Joint Forces Command discussed area JBPO training and a training exercise, Roving Sands/Purple Caduceus 2000. Regarding the discussion of area JBPO training, we agree the training is valuable; however, the discussion did not address organization-level training. Regarding the discussion of the training exercise, we agree that the exercise is an excellent start, but the Joint Staff needs to ensure exercises will continue. The Joint Staff needs to establish a formal process that will ensure training of blood program organizations continues in the future and on an ongoing basis. In response to the final report, we request the Joint Staff provide a plan for ensuring blood program organizations are included in joint- and unified command-level training exercises.

Appendix A. Audit Process

Scope and Methodology

Work Performed. We examined the Blood Program within the Joint Staff and at the blood program offices, the blood program organizations, and the Defense Blood Standard System Project Office. We reviewed management and operational aspects of the blood program activities to determine the readiness of the Blood Program. At all the activities visited we evaluated the integration of the activity with other blood program activities, roles and responsibilities in the Blood Program, readiness planning accomplished, oversight of or by the organization, and roles in determining blood product requirements. In addition, we examined staffing, training, and the red blood cell portion of the frozen blood program at the blood program organizations.

We reviewed DoD, Military Department, and unified command blood program policies dated from August 1988 through August 1999, as well as contingency plans for blood program readiness dated from December 1997 through March 2000. We compiled blood program operations and personnel cost data for FY 1999 from spreadsheets provided by the ASBPO, the Joint Staff, and the Military Departments. We did not assess blood transfusion services at any of the organizations visited or regulatory compliance issues at the BDCs. Because of the relatively small quantity, we did not assess frozen plasma inventory. We did not validate the cost data, the inventory data records provided, or the inventory requirements outlined in the published policies. We did not use computer-processed data for this audit.

DoD-Wide Corporate Level Coverage. In response to the Government Performance and Results Act, the Secretary of Defense annually establishes DoD-wide corporate level goals, subordinate performance goals, and performance measures. This report pertains to achievement of the following goal:

FY 2000 DoD Corporate Level Goal 2. Prepare now for an uncertain future by pursuing a focused modernization effort that maintains U.S. qualitative superiority in key warfighting capabilities. Transform the force by exploiting the Revolution in Military Affairs, and reengineer the Department to achieve a 21st century infrastructure. **(00-DoD-2)**

General Accounting Office High-Risk Area. The General Accounting Office has identified several high-risk areas in DoD. This report provides coverage of the Defense Infrastructure and Defense Inventory Management high-risk areas.

Audit Type, Dates, and Standards. We performed this program audit from October 1999 through August 2000 in accordance with auditing standards issued by the Comptroller General of the United States, as implemented by the Inspector General, DoD. Accordingly, we included tests of management controls considered necessary.

Contacts During the Audit. We visited or contacted individuals and organizations within the DoD, FDA, Veterans Health Administration, and American Red Cross. Further details are available upon request.

Management Control Program Review

DoD Directive 5010.38, “Management Control (MC) Program,” August 26, 1996, requires DoD organizations to implement a comprehensive system of management controls that provides reasonable assurance that programs are operating as intended to evaluate adequacy of the controls.

Scope of Review of Management Control Program. We reviewed the adequacy of the ASBPO and Military Department Surgeons General management controls over inventory management, planning, and training within the Blood Program. We reviewed management’s self-evaluation applicable to those controls.

Adequacy of Management Controls. We identified material management control weaknesses for the ASBPO and Military Department Surgeons General, as defined by DoD Instruction 5010.40, “Management Control (MC) Program Procedures,” August 28, 1996. The ASBPO management controls for Blood Program frozen blood inventory management and the Military Departments management controls for mobilization planning and training were not adequate to ensure that the Blood Program was properly managed to meet readiness requirements. Recommendations A.1., B.1., B.2., and B.3., if implemented, will improve management of the Blood Program.

A copy of the report will be provided to the senior official responsible for management controls in the Offices of the Assistant Secretary of Defense (Health Affairs) and the Military Department Surgeons General.

Adequacy of Management’s Self-Evaluation. The ASBPO, Army, Navy, and Air Force officials did not identify the control weaknesses identified by the audit because they did not identify the Blood Program as an assessable unit in their management control plans. However, in its draft management control program instruction, the Navy has included “blood bank procedures” as an assessable quality assurance unit. The instruction applies to all activities within the Navy Bureau of Medicine and Surgery.

Armed Services Blood Program Office Comments. The ASBPO partially concurred with the Management Control Program issues. They agreed that there was not sufficient oversight of the inventory. However, they indicated that while they are tasked with inventory management, the Services are responsible for mobilization planning and training. They also partially concurred with our assessment of the adequacy of management’s self-evaluation. Specifically, they indicated that the ASBPO and the SBPOs knew about many of the issues discussed in the report and discussed these during the Strategic Planning Conferences held in 1999 and 2000.

Navy Comments. The Navy nonconcurred with the Management Control Program issues. They stated that the Navy was aware of all the issues identified in the report and discussed many during the ASBPO Strategic Planning Conferences in 1999 and 2000. In addition, the Navy stated that direct management oversight is being accomplished by the Navy Surgeon General. The Surgeon General is informed of all blood activities as they occur and played an active role in the management of the Navy blood program.

Audit Response. The ASBPO comments are fully responsive. As a result of the comment on responsibility, we revised the section on Adequacy of Management Controls to reflect ASBPO responsibility for inventory management and the Military Departments responsibility for mobilization planning and training.

We do not agree with the Navy assessment of their management controls. Our identification of the key readiness issues may have prompted discussions at the 2000 conference, but action has not been taken to correct the issues identified in this audit report. We do not believe that the Navy SBPO has adequate oversight of mobilization planning and training for Navy blood program organizations.

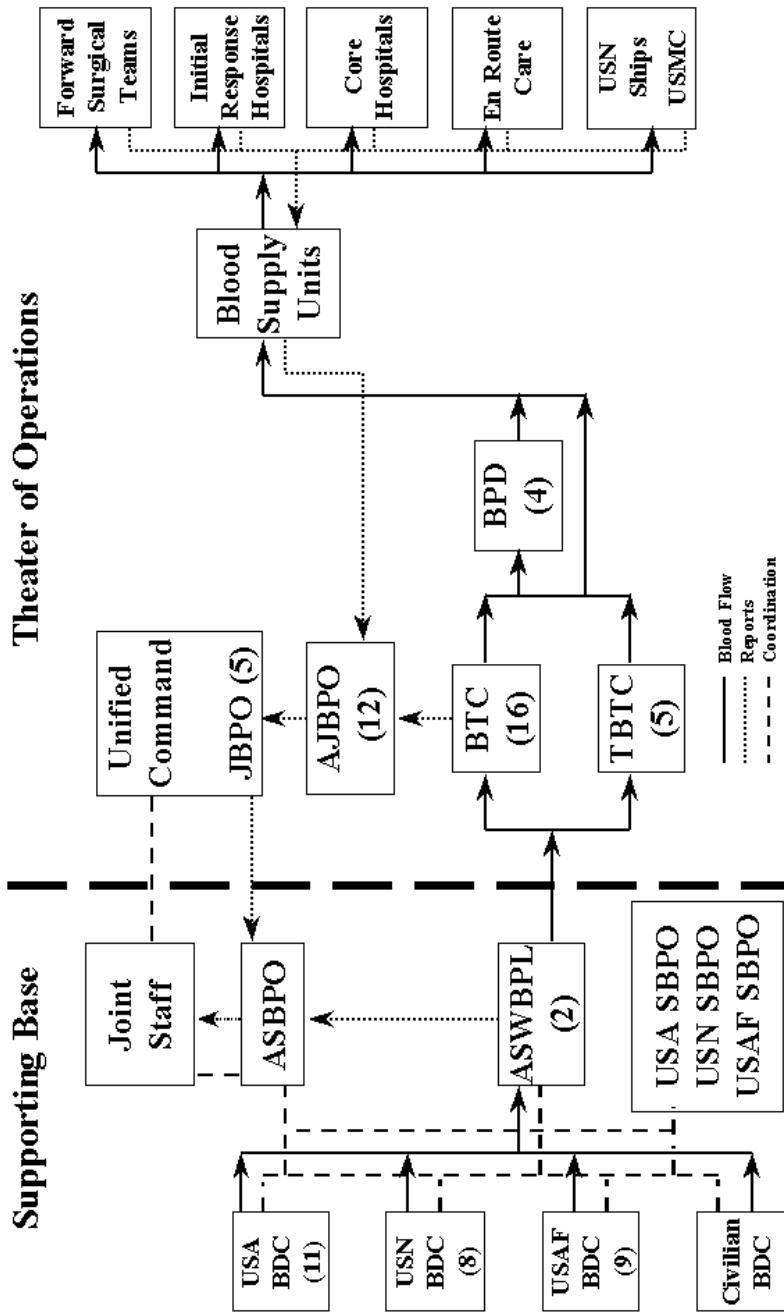
Prior Coverage

Naval Inspector General Report, "Investigation of Blood Banking Procedures at National Naval Medical Center, Bethesda, Maryland, and the Navy Blood Program," October 8, 1998

Air Force Audit Agency, Report No. 26497051, "Management of the Blood Program, 59th Medical Wing, Lackland AFB, Texas (Project 96925105)," August 13, 1997

Systems Research and Applications Corporation "Armed Services Blood Program Management Report," December 18, 1995

Appendix B. Armed Services Blood Distribution System



Note: The numbers in parentheses represent the number of worldwide sites. The number of blood supply units, forward teams, hospitals, and ships depends on the contingency.

Appendix C. Glossary

Area Joint Blood Program Office. The organization outside CONUS responsible for coordinating requirements and distributing blood products to support blood supply units and military treatment facilities in a specific area, regardless of the Military Department, as established by the JBPO.

Armed Services Blood Program. The combined military blood programs of the ASBPO, the individual Military Departments, and the unified commands, in an integrated blood program support system for peacetime, contingency, and war.

Armed Services Blood Program Office. A tri-Service-staffed, joint field operating agency, with the Army as the DoD Executive Agent, responsible for coordination of the Blood Program. Program office responsibilities include ensuring implementation of blood program policies, as established by the Assistant Secretary of Defense (Health Affairs), and standardization of policies, procedures, and equipment. The ASBPO is the overall DoD manager for blood products for the Chairman of the Joint Chiefs of Staff during military contingencies and, when directed by appropriate governmental authorities, for civilian relief efforts.

Armed Services Whole Blood Processing Laboratory. A tri-Service-staffed organization, with the Air Force as the DoD Executive Agent, responsible for the central receipt and confirmation of blood products from CONUS blood banks. The organization is also responsible for the shipment of those products to designated unified commands' BTCs and transportable BTCs.

Blood Donor Center. Military Department-staffed blood organization responsible for the collection and processing of blood products. The BDC may be collocated with a blood bank in a military treatment facility. In a unified command, a BDC may serve as a blood supply unit.

Blood Products. A generic name for blood and blood components, including red blood cells (liquid or frozen), plasma (liquid or frozen), and platelet concentrates.

Blood Product Depot. A Military Department-staffed organization responsible for the strategic storage of frozen blood products in a unified command.

Blood Supply Unit. A Military Department-staffed unit responsible for the receipt and storage of blood products (liquid and frozen) from BTCs, transportable BTCs, or blood product depots. It is also responsible for issuing blood products to military treatment facilities in an assigned geographic area, as directed by an area JBPO. A blood supply unit may be any type unit or facility designated by a Military Department.

Blood Transshipment Center. An Air Force-staffed unit responsible for receiving blood products from an ASWBPL, a blood product depot, another BTC, or a transportable BTC; re-icing the blood products; storing the products; and issuing the products to blood supply units or military treatment facilities, as directed by the area JBPO.

Component Blood Program Office. A Military Department-staffed organization responsible for peacetime coordination and management of a Military Department's blood program within a unified command. For the Navy, that organization may be called the Component Command Blood Program Manager.

Defense Blood Standard System. An automated information system designed to support the Blood Program, the Surgeons General, and the Military Health System readiness goal. System capabilities include blood donor management; blood product management during creation, testing, inventory, and shipment; and patient/transfusion service management.

Deglycerolization. The process of removing glycerol from thawed red blood cells.

Food and Drug Administration. The Government agency that establishes blood banking regulations and requirements for use by blood banks involved in interstate commerce and grants licenses to blood banks complying with those standards. The organization within the FDA that specifically handles blood banking regulations is the Division of Blood and Blood Products in the Center for Biologics Evaluation and Research. The Military Departments comply with those standards and each Military Department Surgeon General holds a license for its respective blood banks.

Glycerolization. The process of adding glycerol to red blood cells prior to initiating the freezing process to prevent ice crystals from forming when frozen.

Joint Blood Program Office. The organization within the unified command surgeon's office responsible for the overall management of blood products in a command theater of operations.

Service Blood Program Office. The organization within a Military Department responsible for the coordination and management of the Military Department's blood program.

Transportable Blood Transshipment Center. Air Force-staffed unit and equipment that can be transported by air, land, or sea to other theater locations. It is used for receiving, re-icing, storing, and issuing blood products. The equipment can be positioned on bare base locations or locations with minimal infrastructure.

Appendix D. Blood Program Policies

DoD Policies.

DoD Instruction 6480.4, “Armed Services Blood Program Operational Procedures,” August 5, 1996, outlines the policies and procedures to carry out the responsibilities of the Blood Program during peacetime, contingency, and wartime operations. The instruction defines responsibilities of the Army as DoD Executive Agent for the ASBPO; the Chairman of the Joint Chiefs of Staff; and the Air Force as the DoD Executive Agent for the ASWBPLs, BTCs, and transportable BTCs. Also, the instruction defines the scope of the Blood Program, which includes the collection, processing, and distribution of blood on a local or regional basis according to Military Department-level policies and the procurement of blood components from non-DoD sources for military use.

Army Technical Manual 8-227-11/NAVMED P-5123/Air Force Instruction 44-118, “Operational Procedures for the Armed Services Blood Program Elements,” September 1, 1995, provides guidance and procedures for collecting, processing, storing, and shipping of blood, as directed in DoD Directive 6480.4. The manual was developed jointly by the Army, Navy, and Air Force. The manual also standardizes the procedures used by the Military Departments, describes the operations of the blood program activities, and identifies the manpower requirements for the ASWBPLs, BDCs, blood product depots, and BTCs.

Army Manual 8-227-12/NAVMED P-6530/Air Force Handbook 44-152, “Joint Blood Program Handbook,” January 21, 1998, identifies the functions and responsibilities of the operating organizations of the Blood Program that could be involved in the management and distribution of blood during a contingency operation. The handbook also identifies procedures for obtaining and receiving blood products and outlines the blood distribution system during a contingency operation.

Army Policies.

Army Regulation 40-3, “Medical, Dental, and Veterinary Care,” July 30, 1999, is the overall Army medical policy for medical care. The regulation includes a chapter that provides the general policies and procedures for the Army Blood Program and outlines the responsibilities of key Army officials in managing the Army Blood Program.

Field Manual 8-10-1, “The Medical Company: Tactics, Techniques, and Procedures,” December 29, 1994, discusses health service logistics, which includes medical supplies and equipment, medical equipment maintenance, blood management, and optical fabrication. The manual outlines how blood is received into theater and supplied within the theater of operations.

Field Manual 8-55, “Planning for Health Service Support,” September 9, 1994, provides guidance to health service support planners at all echelons of care within a theater of operations. The manual includes a chapter on blood management that discusses the overall blood program. The chapter outlines the various blood program offices and their responsibilities, including the ASBPO, SBPOs, JBPOs, and area JBPOs. It discusses blood to be provided at each echelon of care, who is responsible for supplying that echelon with blood, and how each echelon operates within the unified command. It directs planning to be a coordinated effort between the JBPO and the operations and plans personnel of the unified command, and that planning should happen on a continual basis for rapid response to blood support situations.

Navy Policies. OPNAV Instruction 6530.4A, “Department of the Navy Blood Program,” October 14, 1994, provides organizational and operational policies and procedural guidance to implement the Navy Blood Program. The instruction tasks the Secretary of the Navy with the responsibility for the operation of departmental and command blood programs that ensure the proper use of blood resources and enable the Navy and Marine Corps to meet mobilization and contingency requirements for blood and blood products. This responsibility is delegated to the Chief, Bureau of Medicine and Surgery, who also serves as a liaison agent with the ASBPO, the other service SBPOs, and the civilian blood banking community.

Air Force Policies.

Air Force Instruction 44-105, “The Air Force Blood Program,” October 1, 1997, outlines the procedures and standards for managing the Air Force Blood Program. The instruction discusses the overall Air Force Blood Program and the responsibilities of headquarter and base-level blood program organizations. It also describes the activation requirements for the ASWBPLs, Air Force BDCs, the BTCs, and the transportable BTCs.

Air Force Instruction 44-112, “The Air Force Blood Program Technical Memorandums,” November 23, 1994, establishes the procedures and assigns responsibilities for publishing, distributing, and implementing Air Force Blood Program Technical Memorandums.

Unified Command Policies.

U.S. European Command. U.S. European Command Directive 67-4, “USEUCOM Joint Blood Program,” August 22, 1999, provides guidance and responsibilities for the commands and organizations within the USEUCOM area of responsibility. The directive outlines the roles, responsibilities, and procedures for the JBPO, area JBPOs, Component Blood Program Offices, the component commands, and the naval ships within USEUCOM.

U.S. Joint Forces Command. U.S. Joint Forces Command Instruction 6530.2B, “U.S. Joint Forces Command Joint Blood Program,” undated draft, establishes the policy and organization, provides procedural guidance, and assigns responsibilities for the Joint Forces Command’s blood program.

The instruction applies to all Military Departments, subordinate unified commands, joint task forces, and other forces assigned under the operational control of the Commander in Chief of the command.

U.S. Pacific Command. USCINCPAC Instruction 6530.2J, “U.S. Pacific Command Joint Blood Program,” April 20, 1998, (being revised under draft instruction 6530.2K), provides the organizational policy and procedural guidance for the joint blood program within USPACOM. It assigns roles, responsibilities, and authority to the joint blood program activities and describes the coordination of the unified, sub-unified, and component command blood programs. The instruction also gives an operational description of the Blood Program distribution system within USPACOM and gives specific procedures for the operation of the BTCs.

U.S. Southern Command. U.S. Southern Command Regulation 40-5, “SOUTHCOM Joint Blood Program Policy,” April 28, 2000, provides guidance and delineates responsibility and authority concerning the U.S. Southern Command joint blood program. The objective of the policy memorandum is to establish the command’s joint blood program in accordance with the Blood Program standards.

Appendix E. Future Blood Program Initiatives

Frozen Blood Products. Freezing blood products is critical to the success of the Blood Program in the event of a contingency or war. The Military Departments and the unified commands will rely on frozen blood products to support the military treatment facilities until fresh blood is sent from CONUS. The FDA has approved freezing two of the three primary blood products, red blood cells and plasma, but has not approved freezing platelets. However, there are limitations with the freezing and use of thawed red blood cells. The DoD is working to resolve the limitations on frozen red blood cells and trying to obtain approval to freeze platelets. There are no problems associated with freezing and using thawed plasma.

Red Blood Cells. Red blood cells have both a limited frozen and thawed shelf life. Red blood cells' frozen shelf life is currently 10 years, as approved by the FDA. Because the DoD has been freezing red blood cells for more than a decade, much of the frozen red blood cell units in storage is reaching the approved shelf life and expiring. In addition, thawed red blood cells have a short shelf life. Thawed, deglycerolized red blood cells must be used within 24 hours or they must be destroyed.

The DoD is aware of the shelf life problems and working to resolve them. The DoD has a request pending at the FDA to extend the shelf life of frozen red blood cells from 10 to 17 years. The request process began in 1996 when the DoD requested an extension of the shelf life of frozen red blood cells from 10 to 21 years. That request was revised in 1998 for an extension to 15 years and again in 1999 when the latest request was submitted for an extension to 17 years. However, the FDA has not granted an extension because it is concerned with the recovery rate of the red blood cells after thawing and deglycerolization. The DoD is still working with the FDA to obtain approval.

Simultaneously with the request for extension, the DoD is working with two medical supply companies to develop new equipment that would glycerolize and deglycerolize red blood cells using an automated, functionally closed system.* The automated portion of the system would simplify the process, thereby reducing personnel requirements and human errors. The functionally closed aspect of the system would allow for a more sterile environment, and if approved, the thawed red blood cells would have a shelf life of 14 days. While new equipment would solve the second limitation with freezing red cells, it would not solve the first. The first limitation can be temporarily resolved with FDA approval for the extended frozen shelf life; however, a permanent resolution requires an effective frozen blood replacement strategy.

*A functionally closed system is a sterile blood collection and processing system where all connections between the red blood cell product bag and the disposable transfer set are made using a sterile connection, thereby protecting the blood against contaminants.

Platelets. Platelets are not approved by the FDA for freezing and thawing. However, the DoD has submitted a request to the FDA for approval to freeze platelets for up to 2 years. Because fresh platelets have a shelf life of only 5 days, the use of platelets in the theater is limited unless frozen platelets are available. The DoD proposal is actually a two-step process. The first step is to get FDA approval to freeze platelets using dimethylsulfoxide. That process requires removal of the chemical before transfusion in the same way as red blood cells are deglycerolized. The second step, which will not occur until after approval is received by FDA for the first step, is to amend the request using a different procedure that removes most of the chemical before freezing. The platelets can then be used immediately upon thawing as is currently done with frozen plasma.

Future of the Frozen Blood Program. If the DoD receives approval for freezing all three blood products and each blood product has a reasonable frozen and thawed shelf life, how the DoD uses both fresh and frozen blood could be revolutionized. Instead of relying primarily on fresh blood, blood products could be frozen, stored in freezers, and used when needed, during both peacetime and in the event of a contingency or war. Because the three blood products could be stored at the same temperature (-80°C), storing blood products would be simplified.

However, the new approach to a DoD frozen blood program requires the following to be accomplished and accomplishing the tasks is a slow process.

- Approval from the FDA for the extension of frozen red blood cells from 10 to 17 years.
- Approval from the FDA of both steps in the two-step process to freeze platelets.
- Completion of all tests and trials for an automated, functionally closed glycerolization and deglycerolization system and approval of the equipment by the FDA.

Accomplishing the three tasks will take time. For more than 4 years, the DoD has been working with the FDA for approval to extend the shelf life of frozen red blood cells and has not yet received approval. The submission for freezing platelets will be a two-step process and the first step has not been approved. With regard to the third task, one of the two medical supply companies has submitted a package for FDA approval of its automated, functionally closed system, which was only a recent submission. The second company, which has a more efficient system, does not expect to submit a package to the FDA for at least 2 years.

Other Blood Products. Several blood-related products in varying stages of development could also enhance the blood delivery system in peacetime and wartime.

- Hemoglobin-based oxygen carriers, which will be used as blood substitutes.
- Freeze-dried blood products, which will not require thawing and deglycerolization.
- Fibrin bandages, which will reduce blood loss by applying a freeze dried foam to a wound to initiate the clotting process.

The hemoglobin-based oxygen carriers and freeze-dried blood products would minimize or eliminate storage and transportation problems. The fibrin bandage would allow casualties to survive for a longer period of time before blood is needed. According to the ASBPO, those products plus the use of frozen and fresh blood provide the basis for the future of the DoD Blood Program.

Appendix F. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense (Comptroller)
Deputy Chief Financial Officer
Deputy Comptroller (Program/Budget)
Assistant Secretary of Defense (Health Affairs)

Joint Staff

Director, Joint Staff

Department of the Army

Assistant Secretary of the Army (Financial Management and Comptroller)
Surgeon General, Department of the Army
Auditor General, Department of the Army

Department of the Navy

Assistant Secretary of the Navy (Financial Management and Comptroller)
Assistant Secretary of the Navy (Manpower and Reserve Affairs)
Naval Inspector General
Surgeon General, Department of the Navy
Auditor General, Department of the Navy

Department of the Air Force

Assistant Secretary of the Air Force (Financial Management and Comptroller)
Surgeon General, Department of the Air Force
Auditor General, Department of the Air Force

Unified Commands

Commander in Chief, U.S. European Command
Commander in Chief, U.S. Pacific Command
Commander in Chief, U.S. Joint Forces Command

Non-Defense Federal Organizations

Office of Management and Budget
General Accounting Office
Health, Education, and Human Services

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations
House Committee on Armed Services
House Committee on Government Reform
House Subcommittee on Government Efficiency, Financial Management, and Intergovernmental Relations, Committee on Government Reform
House Subcommittee on Technology and Procurement Policy, Committee on Government Reform

Armed Services Blood Program Office Comments



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

ASBPO (40-2b)



18 December 2000

MEMORANDUM THRU THE SURGEON GENERAL, 5109 LEESBURG PIKE
FALLS CHURCH, VA 22041

ASSISTANT SECRETARY OF THE ARMY (MANPOWER & RESERVE AFFAIRS)
THE PENTAGON, WASHINGTON, DC 20310

FOR ASSISTANT INSPECTOR GENERAL FOR AUDITING OFFICE OF THE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE, 400 ARMY NAVY
DRIVE, ROOM 801, ARLINGTON, VA 22202

SUBJECT: Draft Audit Report on Armed Services Blood Program Readiness (Project
No. D2000LF-0028, 1 Sep 00)

1. The Armed Services Blood Program Office (ASBPO) was established by the Assistant Secretary of Defense for Health Affairs to coordinate the blood program of the military services and the Unified Commands. In that role the ASBPO has managed the implementation of a robust frozen blood prepositioning program to meet the needs of the Unified Commands in OCONUS locations.
2. We have reviewed the draft IG Audit Report and identified several areas of concern. Our responses to your findings and recommendations are enclosed. We received the Services responses and they are considered in our response. We request that future audits of the Armed Services Blood Program designate the Office of the Surgeon General of the Army as Executive Agent for the coordination of replies.
3. If you have any questions or require additional information regarding the enclosed response, my POC for this report is Major Ronny Alford and he may be reached at (703) 681-8010.

Encls

G. Michael Fitzpatrick
G. Michael Fitzpatrick
COL, MS, USA
Director, Armed Services Blood Program

**ARMED SERVICES BLOOD PROGRAM RESPONSE TO
DOD IG DRAFT AUDIT REPORT
Armed Services Blood Program Readiness
Project No. D2000LF-0028, 1 Sep 00**

FINDING: FROZEN RED BLOOD CELL INVENTORY MANAGEMENT

RESPONSE: Partially concur with the finding.

COMMENTS:

1. **Partially Concur** with the statement that "DoD blood program offices did not properly manage the frozen red blood cell inventory of the Armed Services Blood Program."

a. We agree that additional FRBC inventory reporting is needed. We will require the Unified Commands to report their inventory status to the ASBPO at least annually. We will also require annual reports from the ASWBPLs and Navy ships through their host MTF storage facility. Additionally, we will require all Blood Product Depots to acquire and use DBSS to track their FRBC inventories. The current spreadsheets used for inventory management at Camp Carroll and Camp Humphries are inadequate for tracking the required data on the FRBC inventory. The Army will be tasked with equipping the Camp Carroll and Camp Humphries BPDs in Korea with DBSS. The Navy has implemented DBSS on the hospital ships but will not implement DBSS on casualty receiving/treatment ships. The ASBPO will require the Navy SBPO to validate and report shipboard inventories annually. These steps will allow us to automate our inventory tracking systems to the extent possible and improve the reliability of the data.

Revised

b. For wartime purposes, we believe our FRBC inventory is adequate in consideration of revised Unified Command OPLAN inventory requirements. We consider our available inventory of FRBCs for wartime to include non-expired units that are either fully tested, or untested but appropriately labeled. Non-expired FRBCs for contingency purposes include all units less than 21 years old.

(1) Regarding untested units, we referred the issue concerning HIV-1 p24 antigen testing to the FDA because of our inability to test some of our FRBC inventory. In an April 8, 1996 memorandum, the FDA gave us three options in order to comply with the testing requirement: (1) destroy the inventory, (2) find the donors and test them with newly collected samples, or (3) label the units to state that they had not been tested for HIV-1 p24 antigen and that the status of the donors was not known. (Encl) The third option did not require us to strike the license from the product; therefore, the ASBPO opted to retain the licensed products with the alternate labeling instructions provided by the FDA. The FDA letter also stated that if we elected the third option, they recommended the units be used only in cases of emergency, including military need. We are retaining those units to meet our contingency requirements. Upon validation of world-

wide inventories, the ASBPO will evaluate the need to redistribute FRBC to evenly disperse units in each category.

(2) Although maintaining FRBCs for 21-years has been established in doctrine (Joint Publication 4-02.1, Joint Tactics, Techniques, and Procedures for Health Service Logistics Support in Joint Operations, 6 Oct 97), we acknowledge that the FDA has not licensed the use of FRBCs over 10 years old and that we have not published an official DoD implementation policy or BPL that allows the use of FRBCs over 10 years old. However, as you identified in your report, the DMSB has approved 21-year old FRBCs for contingency usage and we are planning to retain the blood for that use. In addition, we are working with the FDA on our application to extend the storage life of FRBCs to at least 17 years. We fully anticipate approval from the FDA for the extension. A BPL will be issued stating the policy of FRBC retention for 21-years and the policy will be incorporated in Technical Manual No. 8-227-11, Operational Procedures for The Armed Services Blood Program Elements, 1 Sep 95, in the next review cycle. Estimated completion date: 1 May 01

(3) The MBP 2004 that initiated the frozen blood program should have included a long-range plan to address the eventual replacement of the FRBC contingency stock. We acknowledge that replacement of HIV-1 p24 antigen untested units at the current time would not be practical until the freezing protocols needed to take advantage of new instruments that are pending FDA licensure and offer enhanced efficiency and utilization can be used.

c. The ASBPO has made continuous efforts to refine and improve our FRBC inventory. We recognized that the current system for freezing and deglycerolizing FRBCs was labor intensive and actively engaged industry to bring a new generation of improved systems to fruition. Inventory management will be further refined by the development and implementation of a process which includes a method of the Unified Commands reporting their FRBC inventory and reconciling those inventory reports with the cryovial inventory reports from the ASWBPLs.

d. We acknowledge that after the revised Unified Command inventory requirements are finalized, a new BPL will have to be issued documenting the new requirements. Although FRBC inventory at the ASWBPLs is not linked specifically to any given OPLAN, the ASBPO will issue revised inventory standards to the ASWBPLs specifying the number of FRBC units to be maintained.

2. **Partially Concur** with the statement that “ASBPO did not provide clear policy that standardized identification, use, and disposition of the FRBC inventory.”

a. We acknowledge that in the past there were decisions made that were not well documented or communicated down to operational units. Furthermore, there was a lack of follow-up to ensure that policies were implemented once they had been issued. We are working to improve the communication of policies and procedures and will institute

management controls focused on providing feedback that will allow us to ensure that policies have been appropriately implemented.

b. ASD(HA) did issue a memorandum (10 Jul 96) with specific guidance on the storage, use, disposition, and labeling of non HIV-1 p24 antigen tested FRBCs. The Surgeons General were required to complete the requirements described in the memorandum no later than 31 Dec 96. This memorandum is now obsolete and will be rescinded.

c. The IG report identifies four categories of FRBC inventory reported by the blood program organizations. The terms used are not consistent with the Defense Blood Standard System (DBSS). DBSS allows "Quarantined" blood products to be electronically labeled with additional descriptive terms. The ASBPO did not issue guidance regarding the use of additional descriptive terms for quarantined blood products. The ASBPO will issue specific guidance on the use of descriptive terms for quarantined blood products in DBSS.

d. It is important to note that "quarantined" FRBCs cannot be issued through DBSS unless specific action is taken to take the FRBC out of quarantined status. Additional descriptive terms such as "training", "good", "hold", or "emergency use only" do not effect the quarantined status of the blood product. We are in the process of formulating plans and procedures for quarantined units to be implemented at sites that do not have DBSS available. At a minimum, we will require quarantined units to be physically separated from available inventory. Estimated completion date: 1 Jun 01

3. **Partially Concur** with the statement that "In addition the ASBPO did not establish a plan for replacing the expired or untested inventory."

a. The Plan for replacing FRBC inventory was not formalized as we are several years away from needing to act and we were focusing on improving the product and processes for producing the product. We knew from consultations with the Unified Commands that the inventory requirements would be reduced in future OPLANS. We anticipated that the reduced requirements could be met with fully tested or appropriately labeled units. If not, we will produce enough FRBCs to meet the requirements.

b. Before we initiate any replacement program, we recognize that a complete validation of the inventory is required. We will formulate a plan to validate the inventory and issue that guidance to the Services and Unified Commands.

Deleted

4. **Non-Concur** with the statement that "DoD may not be able to effectively supply blood products to the blood program organizations and forward medical units in the event of a major theater war."

a. Current inventory of fully tested or appropriately labeled FRBCs less than 21 years old is expected to provide complete coverage of the projected Unified Command reduced

OPLAN inventory requirements. If shortfalls are identified, we will require a sufficient quantity of FRBCs to be shipped to meet the requirements.

b. Shortfalls exist in our current capability and the root cause must be determined. Possible causes include inadequate communication, training and the current labor-intensive systems that only allow for 72-hour post-thaw dating. The ASBPO is actively engaged in pursuing emerging technology that will allow us to produce and deglycerolize FRBCs in a closed system. These new technologies that are pending licensure will have a tremendous multiplying effect on improving our readiness capabilities. In addition, the new technology will reduce manpower and documentation requirements while simplifying a labor-intensive process.

c. A real impediment to our success, is insufficient staffing to operate a complex peacetime and wartime system. Although we understand that the staffing of the ASBP will be addressed in a later phase of the IG's review of the ASBP, we must note that insufficient staffing has had a major impact on the issues raised in this report. Personnel issues that must be addressed in order for mission execution are as follows:

(1) Only one Unified Command (USJFCOM) has a full time JBPO co-located with the Unified Command's Surgeons Staff. USPACOM and USEUCOM have part-time JBPOs dislocated from the Unified Command's Surgeons Staff. USSOUTHCOM and USCENTCOM have reservist functioning as their JBPOs. The ASBPO is staffed at only 67% of required action officers. Because none of the war fighting Unified Commands has a full time JBPO, the ASBPO is frequently tasked to provide JBPO functional support out of its already depleted staffing pool.

(2) Staffing in the Service Blood Program Offices is also insufficient. Two person offices are managing programs that require stringent quality assurance and readiness oversight. The entire ASBP has seen a tremendous increase in regulatory requirements levied by the FDA and our historical staffing is insufficient to proactively meet the new requirements and oversee readiness requirements. Without a FDA-licensed system of blood banks, donor centers, and transfusion services we could not support either a peacetime or readiness capability. We acknowledge that readiness oversight may have suffered at the expense of maintaining the peacetime requirements.

RECOMMENDATIONS: FROZEN RED BLOOD CELL INVENTORY MANAGEMENT

RESPONSE: Concur with three recommendations and partially concur with one recommendation.

COMMENTS:

1. **Concur with recommendation A.1.a.:** "We recommend that the Director, Armed Services Blood Program Office, in coordination with the Surgeons General of the Military Departments and the Joint Staff issue policy that: (1) clearly defines the various

categories of blood unit status, such as good, training, quarantined, untested, or expired; (2) requires all categories of blood unit status be reported on the Blood Bank Operational Report; and (3) clearly identifies the use and disposition of each unit, including those with multiple statuses.”

a. The ASBPO and Services have invested a tremendous amount of effort in establishing the computerized Defense Blood Standard System (DBSS). DBSS allows us to subcategorize “quarantined” units. The ASBPO has not issued specific guidance to standardize the further categorization of quarantined units. We recognize that all blood products including FRBCs can be in quarantined status for a number of reasons. The ASBPO will publish specific guidance in the form of a BPL. The BPL will specify the terms to be used and define each term. Additionally, we will specify the proper use and disposition of the units and the priority for use of units during contingencies. Estimated completion date: 1 Mar 01.

b. The latest version of DBSS allows for Joint Medical Asset Repository (JMAR) monitoring of blood bank inventories. This functionality will afford the SBPOs and ASBPO the opportunity to make snapshot verifications of inventory categories and statuses. We anticipate exploiting this capability in the future. The ASBPO will determine procedures and incorporate inventory management in a formal management plan. Estimated completion date: 1 Jul 01.

c. The ASBPO agrees that the Blood Bank Operational Report does not capture enough data regarding the inventory status of FRBCs. The entire report and supporting software will be evaluated by the ABCC. ABCC recommendations will be incorporated in the software update. Estimated completion date: 1 Aug 01

2. **Concur with recommendation A.1.b:** “Develop a plan of action for implementing new tests as the tests are required on frozen blood units in the future. The plan should address additional tests on current frozen inventory and include requirements for testing future blood collections to ensure adequate quantities of collected blood is available when the new tests are required.”

a. Although we do not have a formalized plan for future testing, the managerial processes used in this very fluid and dynamic area are sound. Unfortunately, we are not able to determine the future developments of testing technology but we have a system in place with our cryovials that will serve as the basis of a formalized and documented plan. Key elements of the plan will be the evaluation of new test requirements, matching FRBC units with their cryovial, conducting the test at centralized locations, and finally, matching the results with the FRBC units and appropriately labeling the units. If new tests are required and cryovials are not available, we will request guidance from the FDA and follow their suggested guidance on the use and disposition of those units. We estimate that we will have a comprehensive plan ready for implementation by 1 Jul 01.

b. It is important to note that the cryogenic vials in storage are acceptable for all tests currently mandated by FDA except HIV-1 p24 antigen. Cryovials from the non-

rejuvenated units were acceptable for HIV-1 p24 antigen testing. Cryovials prepared for the rejuvenated units were the only test samples deemed to be unacceptable for HIV-1 p24 antigen testing. No additional preparations could have been made by the ASBPO to prepare for these new tests.

3. Partially Concur with recommendation A.1.c: "Establish management controls to ensure frozen blood inventory requirements are met at all blood storage facilities with fully tested, non-expired frozen blood units."

a. In our opinion, FRBC inventory requirements can be met for contingency purposes with fully tested, or appropriately labeled, non-expired (21-year-old) units.

Revised

b. ASBPO will gather data via the Blood Bank Operational Report regarding the number of units that fall into categories other than available inventory (fully tested, less than 10 years old). Any unit that is not fully tested will be appropriately labeled or quarantined for contingency use if testing can not be accomplished. Estimated Completion Date: 1 Aug 01

c. ASBPO will continue to pursue acquisition of new freezing systems as the FDA licenses them. The Services have all been advised to budget for these acquisitions. After approval of the new equipment, the ASBPO will publish FRBC replacement inventory requirements and task the Services to provide the necessary number of units to meet them.

d. ASBPO will actively manage the FRBC disposition instructions issued to the Services as action is received from the FDA regarding our shelf-life extension application. FRBC units greater than 10 but less than 17 years old (if approved by FDA) will be moved from quarantined status back into available inventory status. Appropriate guidance to accomplish this task will be coordinated with the SBPOs and issued to the field.

e. ASBPO will remain actively engaged with industry (Haemonetics and Mission Medical), Navy Blood Research Laboratory, and Walter Reed Army Institute of Research to ensure that any new FRBCs prepared for our inventory are compatible with new technological advances in freezing and deglycerolization protocols. We are committed to fielding a FRBC preparation system that will provide at least 14 days of post-thaw shelf life.

4. Concur with recommendation A.2.: "We recommend that the Assistant Secretary of Defense (Health Affairs), in coordination with the Surgeons General of the Military Departments, study the feasibility of using frozen blood in peacetime and, if feasible, develop an implementation plan."

a. We do not feel that it would be feasible to work this issue until the instruments pending FDA licensure are available for use. Current FDA licensed 24-hour post-thaw dating does not meet the needs of our peacetime transfusion services.

Revised

- b. Once we have a licensed 14-day post-thaw deglycerolized blood product available, the ASBPO will coordinate with the Services to study the feasibility of using the product in our busier transfusion services. Estimated completion date: 1 Mar 02

FINDING: MOBILIZATION PLANNING AND TRAINING

RESPONSE: Concur with the finding.

COMMENTS: Concur with the statement that “DoD needs to improve mobilization planning and training for the Blood Program.”

1. A critical part of the ASBPO Management Plan will be annual assessments from the Services and Unified Commands. Mobilization plans will be reviewed for details regarding units tasked to operate elements of the ASBP and their training status. Other critical elements that we will review are equipment and supplies for the units and the frequency of exercises.

2. Although the IG report correctly identified that the ASBPO does not need a mobilization plan, we will incorporate the readiness of our two IMA personnel in our management plan. The chart on page 17 of the draft report misleads the reader into thinking that the ASBPO requires a plan. Suggest that an additional column designating the organizations required to have a mobilization plan be added to the chart or some other change to clarify the issue.

RECOMMENDATIONS: MOBILIZATION PLANNING AND TRAINING

RESPONSE: Concur with two recommendations and partially concur with one recommendation.

COMMENTS:

1. **Concur with recommendation B.1.a,b.:** “We recommend the Surgeons General of the Military Departments establish management control to ensure that (1) All blood program organizations with contingency or mobility missions prepare written mobilization plans, identify augmentation or backfill sources, and adequately train their staff; (2) All active duty personnel assigned to augment or backfill blood program organizations are trained in their mobility mission; and (3) Reserve units assigned to augment or backfill blood program organizations are trained in their mobility mission and, whenever possible, train at their mobility site or one similar.”

2. **Partially Concur with recommendation B.2:** “We recommend the Surgeons General of the Navy and Air Force require its blood program office to prepare mobilization planning documents that include establishing blood quotas and identifying mobilization staffing sources.”

Revised

a. As noted on page 16, paragraph 5 of the audit report, “All three SBPOs established blood quotas; however, only the Army had written reports that identified mobilization staffing sources.” Since all three SBPOs (Army, Air Force, and Navy) established quotas for blood collections, freezing and contingency support, clarification is needed.

b. The ASBPO agrees that all elements noted in the recommendation should be included in each Service’s mobilization plans. We also fully support the identification of mobilization staffing. Once identified, we also support exercising those personnel and equipment packages.

3. **Concur with recommendation B.3.:** “We recommend that the Director, Joint Staff, in coordination with the unified commands and the Military Departments, incorporate blood program distribution and processing into joint and unified command-level training exercises.”

a. We strongly support realistic exercises to test the ASBP system.

b. The ASBPO staff is working closely with the Joint Staff J-4 MRD to incorporate blood play into JCS-directed exercises. However, scenarios are sometimes removed during exercise refinement. The ASBPO would like to see our personnel, equipment, and plans exercised in JCS-directed exercises. The ASBPO will continue to attempt to get blood play in JCS-directed exercises, but we must have Unified Commands and JBPOs insert critical blood play into Unified Command exercises. We will continue to work blood play into all JCS-directed exercises from our level.

c. The Unified Commanders and their staffs (JBPOs in particular) are tasked by DODI 6480.4 to ensure that blood services medical readiness requirements are identified and that DoD capabilities are adequate to meet those requirements. Additionally, the services establish exercise and training requirements for their organizations. The ASBPO will request certification of mobilization planning and training to be a part of the annual assessments conducted by the Services and Unified Commands in accordance with their management control plans.

FINDINGS: MANAGEMENT CONTROL PROGRAM REVIEW:

RESPONSE: Partially Concur with the Management Control Issues.

COMMENTS:

1. **Partially Concur** with the following statement: “The ASBPO and Military Department Surgeons General management controls for Blood Program frozen blood inventory management, mobilization planning, and training were not adequate to ensure that the blood program was properly managed to meet readiness requirements.”

a. We concur that there has not been sufficient oversight or follow-up of blood programs in the Unified Commands. We feel that this was caused by the organizational

Revised

structure of the ASBP and the lack of JBPOs assigned to and co-located with the Unified Command staffs. The ASBPO will produce and implement a management plan that will correct this discrepancy. Estimated completion date: 1 Sep 01

b. We agree that ASBPO is tasked with oversight of inventory management and that the Services are tasked to perform mobilization planning and training.

2. **Partially Concur** with the following finding: "The ASBPO, Army, Navy, and Air Force officials did not identify the control weaknesses identified by the audit because they did not identify the Blood Program as an assessable unit in their management control plans."

a. The ASBPO and the SBPOs knew many of the issues identified in the report and discussed during the ASBP Strategic Planning Conferences held in 1999 and 2000. Several IG Auditors attended the 1999 planning conference and had the opportunity to hear our discussions regarding plans to resolve the issues.

b. DODI 5010.40, Management Control (MC) Program Procedures, defines an assessable unit as "any organizational function programmatic or other applicable subdivision, capable of being evaluated by MC assessment procedures." The ASBPO is a joint FOA and as such does not have any subordinate units to assess. Although the ASBPO is charged with control of policy, operational control of ASBP organizations rests with the Services and Unified Commands. The ASBPO will seek to include inventory management in the OTSG Management Control Program Plan. Estimated completion date: 1 Sep 01

c. The ASBPO will require oversight of all blood program organizations and require the Services and Unified Commands to report inventory and training annually. Estimated completion date: 1 Nov 01

Joint Staff Comments

Final Report
Reference



THE JOINT STAFF
WASHINGTON, DC

Reply ZIP Code:
20318-0300

DJSM-956-00
16 November 2000

MEMORANDUM FOR THE INSPECTOR GENERAL, DEPARTMENT OF DEFENSE

Subject: Audit Report on Armed Services Blood Program Readiness (Project No. D2000LF-0028) (formerly OLF-0196)

1. Thank you for the opportunity to coordinate on the subject audit report.¹ We use the Armed Services Blood Program Office (ASBPO) as our functional expert on issues dealing with the blood program. ASBPO will be responding directly to your office because there are many parts of the draft report to which it takes issue. Based on ASBPO's concerns (Enclosure A), we recommend that your staff and the ASBPO staff meet, resolve the differences, and restaff the draft report. We have also included comments from USJFCOM (Enclosure B) and the Air Force (Enclosure C), which also take issue with the draft report.
2. The Joint Staff point of contact is Lieutenant Colonel Kenneth Weltz, 693-5101.

See Pages
43-52

See Pages
63-65

A handwritten signature in black ink, appearing to read "Garry R. Trexler".

GARRY R. TREXLER
Major General, USAF
Vice Director, Joint Staff

Enclosures

Reference:

1 Draft of a Proposed Audit Report on Armed Services Blood Program Readiness, 1 September 2000, Project No. D2000LF-0028 (formerly Project No. OLF-0196)

Weltz, Kenneth R., Lt Col, J4
From: Mettelle, Frank C. LCDR/USN [J02M7@hq.jfcom.smil.mil]
Sent: Tuesday, October 10, 2000 11:29 AM
To: 'kenneth.weltz@is.pentagon.smil.mil'
Subject: SJS 00-04814 ASBPO AUDIT RESPONSE
CLASSIFICATION:UNCLASSIFIED

Sir,

US Joint Forces Command (US JFCOM) has reviewed the Audit Report on Armed Services Blood Program Readiness (Project No. D2000LF-0028) (formerly OLF-0106) and provides the following response:

Concur with the findings of the report and agree the recommendations including the material control weaknesses, with the following exceptions:

- 1) The report fails to mention the Memorandum of Agreement between US JFCOM (former U.S. Atlantic Command) and Armed Service Blood Program Office on Area Joint Blood Officers (AJBPOs) Training, signed Sep/Nov 1999. The MAU was established as the means to train and maintain joint training of laboratory officers from all services, both Active and Reserve, who would deploy in support of Unified Command theater blood distribution system elements. The first AJBPO training course was conducted 05-16 June 00, with five officers attending (1 active Air Force, 3 active Army, and 1 one reserve Army). Academic and practical demonstration topics covered included: blood distribution assets, Service capabilities, drafting an appendix 2 (Joint Blood Program) for an Annex Q (Medical Services), and theater support of class VIIIB supplies. Training programs and initiatives such as this, significantly increases ASBPO readiness capabilities.
- 2) The report fails to mention exercise Roving Sands/Purple Caduceus 2000 held at Camp Lejeune, NC 09-23 Jun 00. This exercise, conducted by US JFCOM, coordinated the largest blood distribution exercise since the mobilization of ASBPO assets during Desert Shield/Desert Storm. Over 6000 units of simulated blood were moved from the Armed Services Whole Blood Processing Laboratories (ASWBPL) East and West to the hospital ship USNS COMFORT and to the 32nd MedLog Blood Supply Unit (BSU). The BSU coordinated the distribution of the simulated units to seven level II and III Medical Treatment Facilities (MTF) where it was used to augment the treatment of simulated casualties. Additionally, a Joint Blood Program Office (JBPO) in support of the Joint Task Force was established for command, control and management of two theater sized blood distribution programs. This exercise successfully accomplished the objectives of standing up a JBPO; employing blood distribution assets to the field; exercising class VIIIB shipping, storage and distribution; exercising the blood reporting system; facilitating the simulated casualty testament at level II and III MTFs; and demonstrating and evaluating blood bank personnel competency and equipment reliability.

v/r LCDR Mettelle

LCDR F.C. METTILLE
JOINT BLOOD PROGRAM OFFICER
U.S. JOINT FORCES COMMAND J02M7
DSN 836-6382 COM 757-836-6382

ENCLOSURE B

Department of the Army Comments



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258



MCHO-CL-R

8 JAN 2001

MEMORANDUM THRU ASSISTANT SECRETARY OF THE ARMY (MANPOWER &
RESERVE AFFAIRS), PENTAGON, WASHINGTON,
John P. McLaurin III
DC 20310

**Deputy Assistant Secretary
(Military Personnel Policy)**

FOR ASSISTANT INSPECTOR GENERAL FOR AUDITING OFFICE OF THE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE, 400 ARMY NAVY
DRIVE, ROOM 801, ARLINGTON, VA 22202

SUBJECT: Draft Audit Report on Armed Services Blood Program Readiness (Project
No. D2000LF-0028, 1 Sep 00)

1. The U.S. Army Blood Program concurs with the Armed Services Blood Program Office (ASBPO) response submitted to Finding A "Frozen Red Blood Cell Inventory Management" and Finding B "Mobilization Planning and Training" (Enclosure 1).
2. The following responses are submitted to the report from the Army Blood Program:
 - a. We agree with recommendation A.3. Following the development of a plan by the ASBPO to replace expired and untested frozen units, a funding request will be submitted.
 - b. We agree with recommendation B.1. and paragraphs a, b, and c. The Army Blood Program has actively worked on realignment /missioning and training of the reserve components supporting the Army Blood Program. Two separate documents were submitted with cover memorandums, dated 4 May 2000 (Enclosure 2) and 7 April 2000 (Enclosure 3), to demonstrate Task Assessment/Training Strategy and Annual Training occurring in the reserve components. Additionally, an organizational mobilization assessment tool (Enclosure 4) was recently submitted to individual blood donor centers to aid in the evaluation of each organization's readiness posture and mobilization mission requirements.

Printed on Recycled Paper

MCHO-CL-R

SUBJECT: Draft Audit Report on Armed Services Blood Program Readiness (Project No. D2000FL—0028, 1 Sep 00)

3. Our point of contact is LTC Dennis A. Stewart, Army Blood Program Manager, Office of Assistant Chief of Staff for Health Policy and Services, DSN 471-6344 or Commercial (210) 221-6344.

FOR THE SURGEON GENERAL:

4 Encls
as



PATRICK D. SCULLEY
Major General
Deputy Surgeon General

Department of the Navy Comments



DEPARTMENT OF THE NAVY
OFFICE OF THE ASSISTANT SECRETARY
(MANPOWER AND RESERVE AFFAIRS)
1000 NAVY PENTAGON
WASHINGTON, DC 20350-1000

MEMORANDUM FOR THE DEPARTMENT OF DEFENSE INSPECTOR GENERAL

SUBJECT: Armed Services Blood Program Readiness - ACTION
MEMORANDUM

In response to Attachment 1, the subject draft publication has been reviewed. The Department of the Navy comments are provided in Attachment 2. In addition, DON concurs with the Armed Services Blood Program Readiness comments provided in Attachment 3.

My point of contact is Mr. Rick Barnish, Bureau of Medicine and Surgery and can be reached at (202) 762-3336 or email: JRBarnish@us.med.navy.mil.

Karen S. Heath

KAREN S. HEATH
Principal Deputy
Assistant Secretary of the Navy
(Manpower and Reserve Affairs)

Attachments:

1. DODIG Draft Report: Armed Services Blood Program Readiness
2. Department of the Navy comments
3. Armed Services Blood Program draft comments for ASD (HA)

Deleted

Revised

**NAVY SURGEON GENERAL RESPONSE TO
DOD IG DRAFT AUDIT REPORT
Armed Services Blood Program Readiness
Project No. D2000LF-0028 dtd 1 September 2000**

FINDING: FROZEN RED BLOOD CELL INVENTORY MANAGEMENT

RECOMMENDATION A.1: Partially concur with comments.

COMMENTS: Concur with and support the comments in ASBPO's attached response and provide the following additional Navy comments.

- Clarification is needed to the statement on page 9 of this report that ASBPO did not issue clear guidance regarding the use and disposition of non HIV AG tested units.
 - ASBPO and the Navy issued policy, specifically explaining the disposition and use (emergency/contingency) of non-HIV Ag tested units. (BUMED ltr 4 Jun 96, ASD (HA) ltr 10 Jul 96, and BUMED ltr 5 Aug 96).
- Clarification is needed to the discussion on pages 6, 7, and 8 of this report regarding frozen blood requirements for Navy facilities in the OPNAVINST 6530.4A, Oct 1994.
 - The OPNAV instruction, a Service instruction, does not expand on ASBPO and Unified command requirements. Service policies and instructions are written in support Unified command requirements.
 - ASBPO Blood Program Policy Letter 98-7 revised and reduced requirements for EUCOM Navy facilities to 6000 units.
 - PACOM Draft Appendix 2 to Annex Q dtd March 2000 of USPACOM OPLAN 5027-98 revised and reduced requirements for PACOM Navy facilities. (Classified)
 - ASBPO and Unified command requirements (higher authority) superceded OPNAVINST 6530.4A requirements. Unified Command frozen blood requirements in the OPNAV instruction are no longer valid.
 - Recent consolidation Navy consolidations and closure have rendered the MTF requirements in the OPNAV instruction invalid.
 - BUMED ltr 6530/20.1 Ser 27/0150 of 24 Oct 2000 recently revised the OPNAV frozen blood requirements for CONUS MTFs. Portsmouth, Bethesda, and San Diego are now only required to maintain a minimum of 1000 units of frozen blood, but maintain a 2000 unit storage capability. This allows the MTFs to maintain the capability to function as a secondary storage facility for CRTS and TAHs for offloading frozen inventory when ships undergo repair.
 - The OPNAVINST 6530.4A is currently under revision to accurately reflect Unified command, ASBPO, Navy shipboard, and revised MTF requirements.
 - EUCOM Frozen Blood Inventory is appropriate. Navy inventory currently exceeds the revised requirements of ASBPO 98-7 letter.
 - PACOM Frozen Blood Inventory is appropriate. Navy inventory currently exceeds the revised USPACOM OPLAN requirements.

Revised

- Inconsistencies in inventory reporting methods to the DoD IG and the Navy Blood Program, make precise assessment of real time inventory levels difficult at this time.
 - Some units in MTF inventories were “designated” for specific ships and reported as ship’s inventory, even though the units are not currently onboard the ship. The Navy Blood Program is aware and will issue guidance to standardize reporting of units physically in inventory. Inventory will not be “designated” for ship inventory. Only units physically onboard the ship or in MTF inventory will be counted and reported.
 - **However, the Navy Blood Program has determined that there is an adequate number of frozen units available in frozen blood storage facilities to meet simultaneous full mobilization requirements for all LHAs, LHDs, and TAHs.**
 - **There are currently over 25,000 frozen units prepositioned at various Navy CONUS MTFs, Navy frozen blood product depots, and at USAF ASWBPLs to provide the additional 12,000 units required to meet Navy’s full mobilization frozen blood requirements.**

RECOMMENDATION A.2: Concur with comments.

COMMENTS: Concur with and support the comments in ASBPO’s attached response and provide the following additional Navy specific comments.

- ASBPO BPL 93-10 recommended and authorized routine peacetime use to control outdating and elimination of wastage, and supplement the blood supply.
- Navy supports the use of frozen blood in peacetime and did issue guidance for peacetime utilization of frozen blood inventory. BUMED letters of 5 May 97 and 12 Aug 97 strongly encouraged utilization of frozen blood inventory to “effectively manage a valuable resource during peacetime.” Navy MTFs were told to utilize frozen blood to augment inventories during blood collection shortfalls and/or increased clinical demands. Use of frozen blood at Navy Medical Centers is a universally accepted practice for inventory augmentation and autologous donations.
- Complete stock rotation to use expiring blood products, although ideal, is not a feasible solution and would be very costly to implement.
- Frozen blood product depots have the majority of frozen units, however, there is either no MTF located with the BPD or the MTF does not routinely use enough blood products to rotate all the stock.
- Frozen blood consumables are costly.
- Deglycerolization supplies stocked for contingency, if used, must be replaced.
- Frozen blood would have to be shipped (cost of shipping and dry ice) to MTF facilities that utilize large quantities of red cells.
- Manpower must be available to thaw, deglycerolize, and prepare red cells.

RECOMMENDATION A.3: Concur with comments.

COMMENTS: Concur with and support the comments in ASBPO's attached response and provide the following additional comments.

- Funding must be provided in future budgets for replacing current frozen blood inventory. However, this replacement plan will be designed to replace units only after they have reached a 21 year dating period and will only be replaced with units frozen using the new freezing/deglycylng technology and equipment to ensure 14 day post thaw shelf life. Thus, funding recommendations must also include continuation of DoD supported frozen blood deglycylng technology research in order to make the equipment available in a time frame that will allow staged replacement of inventory over a number of years.
- The Navy Blood Program did develop an interim plan to replace units that were utilized during peacetime for training and patient transfusion.
- BUMED letters of 5 May 97, 27 Jun 97, and 12 Aug 97 set monthly freezing quotas and established Centers of Excellence for frozen blood manufacturing.
- BUMED msg 160041Z Sep 98 revised previously established red cell freezing quotas. However, NBP freezing centers experienced difficulty in obtaining a sufficient quantity of excess red cells to meet required quotas.
 - Quotas were not met due to decreasing staffing levels, decreasing blood collections at freezing centers, increasing blood usage, and a change in focus on new technologies to automate the freezing/deglycylng process and allow 14-day post thaw shelf life.
 - The Navy has experienced problems with the availability of 800ml collection bags required to freeze red cells. Since the military is the only user of the 800ml bag, there were problems with blood bag production and the number of bags expected to be used by military facilities over a period of time.
 - To help improve peacetime inventory management and decrease red cell expirations, the Navy and other services obtained licensure for use of alternative blood collection bags with 42-day storage additive solutions. Blood collected in these bags could not be frozen by the current technology. This created a requirement for dual inventory of blood bags and collection and processing procedures and a decrease in the number of units available for freezing.
 - ASBPO instructed the services to discontinue the procedure of red cell rejuvenation at the end of storage because of increased hemolysis experienced by those conducting deglycylng research. Thus units had to be frozen within 6 days of collection instead of rejuvenating units that were near expiration. This led to a decrease in the number of units available for freezing.
- After recent BDC consolidations, BUMED message, 18 Sep 00, recently revised frozen red cell freezing quotas, maintaining the requirement to freeze red cells.

- o BUMED ltr Ser 273/0150 Oct 00 established two red cell freezing centers and revised frozen blood inventory requirements for Navy MTFs with BDCs. This letter thus revised the OPNAVINST 6530.4A frozen blood storage/stoggae requirements.

Revised

MOBILIZATION PLANNING AND TRAINING

RECOMMENDATIONS: Partially concur with comments.

COMMENTS: Concur with and support the comments in ASBPO's attached response and provide the following additional Navy comments.

- Clarification is needed to the statements regarding quotas and preparation of mobilization planning documents. BUMED does require identification of mobilization staffing sources and does establish blood quotas. Clarification is needed if the intent of the recommendation is to ensure that Navy mobilization planning documents delineate responsibility for establishing quotas (Navy Blood Program) and include specific requirements for identification of blood donor center and ASWBPL mobilization staffing sources.
- Requirements to identify overall mobilization staffing sources are covered in the BUMED instruction 6440.5B, Medical Augmentation Program (MAP). This was recently revised on 30 May 00 to include implementation of Component UICs for mobilization platforms, including BDC Component UICs.
- BUMED is aware, however, that personnel have not been consistently and officially identified and trained to operate and augment BDCs or mobilize to ASWBPLs. Corrective action to the deficiencies has been planned through the implementation of BDC Component UICs. Full implementation of BDC Component UICs is expected by the end of FY 01.
- Navy Medicine and BUPERS recently re-organized medical personnel augmentation platforms and program management to improve readiness, improve training, and ensure consistency of augmentation personnel assigned to platforms. New program aligned each personnel augmentation platform requirement to Component UICs, including BDC Component UICs.
- Personnel are assigned to a mobilization platform on PCS orders and remain on that platform for the entire term of their PCS to improve platform readiness, consistency, unit cohesion, and training.
- Since BDCs were not included in the original Component UIC concept, NBP determined that BDC personnel were being assigned to other readiness platforms, that BDC augmentation teams were no longer being maintained, and that BDC readiness was less than optimum after implementation of Component UICs for other medical platforms.
- Feb 00: Navy Blood Program Office requested establishment of BDC Core Component UICs.

Revised

- Mar 15, 00: BUMED Tiered Readiness IPT approved establishment of BDC Core Component UICs.
- Mar 28, 00: BUMED Medical Readiness Oversight Committee approved establishment of BDC Core Component UICs.
- BUMED MAP instruction 6440.5B was updated to include BDC CCUIC concept and non-deployable status of BDC personnel.
- Apr 00: BUMED-15/NBP initiated development of BDC staffing standard to standardize peacetime and mobilization requirements for BDC operations.
- Staffing standard is expected to be completed by Dec 00.
- Personnel staffing and training requirements can then be developed and the readiness status can be monitored in conjunction with other medical readiness personnel augmentation platforms in MED-27.
- The Navy plans to prepare additional mobilization planning documents.
 - A new BUMED BDC Mobilization instruction will be developed. Each facility will then be required to develop its own support plan. The plan will clearly define Navy Blood Program responsibilities, identify MTF responsibilities, identify how the BDCs shall operate during mobilization, and list specific instructions and actions to be taken in case to meet established quotas. A staffing standard will be included along with staff and augmentation team training requirements.
 - New Navy Blood Program BDC Mobilization instruction is being written to provide guidance to BDCs. Expected to be available by April 2001.

MANAGEMENT CONTROL PROGRAM REVIEW:

RECOMMENDATION: Non concur with comments.

COMMENTS: Concur with and support the comments in ASBPO's attached response and provide the following additional Navy comments.

- **Non concur** with the following finding: "The ASBPO, Army, Navy, and Air Force officials did not identify the control weaknesses identified by the audit because they did not identify the Blood Program as an assessable unit in their management control plans."
- The Navy has been aware of all of the issues identified in the report and discussed many of these issues during the ASBPO Strategic Planning Conferences in 1999 and 2000.
- Direct management oversight of the Navy Blood Program is accomplished by the Navy Surgeon General and MED-02. The SG requires that he be informed of all significant blood program activities as they occur and requires a quarterly blood program update of progress made on the established NBP POA&M. Additionally, the SG has played an extremely active role, taken a proactive approach to the management of the Navy Blood Program, and provided a high level of support to meet blood program Quality Assurance objectives

Department of the Air Force Comments

Final Report
Reference



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON, DC

29 September 2000

MEMORANDUM FOR ASSISTANT INSPECTOR GENERAL FOR AUDITING
OFFICE OF THE INSPECTOR GENERAL
DEPARTMENT OF DEFENSE

FROM: HQ USAF/SGX
110 Luke Avenue, Room 400
Bolling AFB, DC 20332-7050

SUBJECT: Audit Report on Armed Services Blood Program Readiness (Project No D2000LF-0028) (Formerly OLF-0106)

This is in reply to your memorandum requesting the Assistant Secretary of the Air Force (Financial Management and Comptroller) provide Air Force comments on the subject report.

We concur, with comments, on the findings of this report:

USAF-1. Major. Page ii, para 4, lines 4-6. **Change to read:** “We recommend that the Surgeons General of the Navy and Air Force require its blood program office to prepare mobilization planning documents that include the establishment of blood quotas and identification of mobilization staffing sources.” **RATIONALE:** This statement as written, in the Executive Summary, is misleading and inaccurate. The report states as a finding on page 16, para 5, lines 7-8 that “All three SBPOs (Service Blood Program Offices) established blood quotas; however, only the Army had written reports that identified mobilization staffing sources.” This accurately reflects that the Air Force Blood Program Office had not identified mobilization staffing sources in its mobilization planning documents but has established blood quotas. This report did not identify any issues that were unknown to the Air Force. Many were identified at the Armed Services Blood Program Strategic planning meetings held in November 1999 and February 2000. DoD IG staff were present at both these meetings. The assignment of augmentation forces, through Medical Resource Letters, is an ongoing process that had been addressing the findings of this audit as it was being conducted.

Revised

USAF-2. Substantive. Page 16, para 5, lines 5-9. **Change to read:** “Although the SBPOs do not need to prepare formal plans, they should complete mobilization planning documents that at a minimum establish blood quotas and identify mobilization staffing sources. All three SBPOs established blood quotas; however, only the Army had written reports that identified mobilization staffing quotas.” **RATIONALE:** Eliminate contradictory statement and accurately reflect finding.

Revised
Page 19

Revised
Page 21

2

USAF-3. Substantive. Page 18, para 4, lines 2-4. **Change to read:** “At a minimum, the Navy and Air Force SBPOs should be required to establish blood quotas and identify mobilization staffing sources as required by the Army SBPO.” **RATIONALE:** Eliminate contradictory statement and accurately reflect finding.

Revised
Page 26

USAF-4. Substantive. Page 20, para B.2, lines 1-3. **Change to read:** “We recommend the Surgeons General of the Navy and Air Force require its blood program office to prepare mobilization planning documents that include establishing blood quotas and identifying mobilization staffing sources.” **RATIONALE:** Eliminate contradictory statement and accurately reflect finding.

Page 16

Comments regarding the recommendations and proposed plan of action are as follows:

USAF-5. Concur. Page 14, Recommendation A.2. “We recommend that the Assistant Secretary of Defense (Health Affairs), in coordination with the Surgeons General of the Military departments, study the feasibility of using frozen blood in peacetime and, if feasible, develop an implementation plan.” **Corrective Action:** We agree to coordinate with the Assistant Secretary of Defense (Health Affairs) and the Surgeons General of the Navy and Army to study the feasibility of using frozen blood in peacetime. Estimated date of completion: April 2001.

Page 17

USAF-6. Concur. Page 14, Recommendation A.3. “We recommend that the Surgeons General of the Military Departments include funding in future budgets for replacing expired and untested frozen red blood cell units.” **Corrective Action:** Once the Armed Services Blood Program Office has established a plan for replacing these units and provides cost estimates, we will request funding for replacement of these frozen red blood cell units. Estimated date of completion: September 2002.

Page 23

USAF-7. Concur. Page 20, Recommendation B.1.a.(1). “We recommend the Surgeons General of the Military Departments establish management controls to ensure that all blood program organizations with contingency or mobility missions prepare written mobilization plans.” **Corrective Actions:** Air Force Instruction (AFI) 41-106, Medical Readiness Planning and Training, establishes the requirements for mobilization plans. US Air Force Inspection Agency (HQ AFIA/SG) is tasked in this AFI to evaluate unit implementation of medical readiness policies and procedures to include ensuring that all blood program organizations with contingency or mobility missions prepare written mobilization plans. HQ AFIA/SG will be tasked to provide HQ USAF/SGX with their findings from their biennial evaluations. Estimated date of completion: December 2002.

Page 23

USAF-8. Concur. Page 20, Recommendation B.1.a.(2). “We recommend the Surgeons General of the Military Departments establish management controls to ensure that all blood program organizations with contingency or mobility missions identify augmentation or backfill sources.” **Corrective Actions:** Air Force Instruction (AFI) 41-106, Medical Readiness Planning and Training, establishes the requirements for writing mobilization plans to include identifying augmentation or backfill sources. US Air Force Inspection Agency (HQ AFIA/SG) is tasked in this AFI to evaluate unit implementation of medical readiness policies and procedures to include ensuring that all blood program organizations with contingency or mobility missions prepare written mobilization plans. HQ AFIA/SG will be tasked to provide HQ USAF/SGX with their findings from their biennial evaluations. Augmentation sources are identified in Medical

3

Resource Letters and updated at semiannual meetings in April and November. Estimated date of completion: December 2002.

Page 23

USAF-9. Concur. Page 20, Recommendation B.1.a.(3). "We recommend the Surgeons General of the Military Departments establish management controls to ensure that all blood program organizations with contingency or mobility missions adequately train their staff." **Corrective Actions:** Air Force Instruction (AFI) 41-106, Medical Readiness Planning and Training, establishes the requirements for mobility training. US Air Force Inspection Agency (HQ AFIA/SG) is tasked in this AFI to evaluate unit training and the documentation of this training. HQ AFIA/SG will be tasked to provide HQ USAF/SGX with their findings from their biennial evaluations. Estimated date of completion: December 2002.

USAF-10. Concur. Page 20, Recommendation B.1.b. "We recommend the Surgeons General of the Military Departments establish management controls to ensure that all active duty personnel assigned to augment or backfill blood program organizations are trained in their mobility mission." **Corrective Actions:** Air Force Instruction (AFI) 41-106, Medical Readiness Planning and Training, establishes the requirements for mobility training. US Air Force Inspection Agency (HQ AFIA/SG) is tasked in this AFI to evaluate unit training and the documentation of this training. HQ AFIA/SG will be tasked to provide HQ USAF/SGX with their findings from their biennial evaluations. Estimated date of completion: December 2002.

Page 25

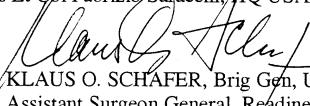
USAF-11. Concur. Page 20, Recommendation B.1.c. "We recommend the Surgeons General of the Military Departments establish management controls to ensure that reserve units assigned to augment or backfill blood program organizations are trained in their mobility mission and, whenever possible, train at their mobility site or one similar." **Corrective Actions:** Air Force Instruction (AFI) 41-106, Medical Readiness Planning and Training, establishes the requirements for mobility training. US Air Force Inspection Agency (HQ AFIA/SG) is tasked in this AFI to evaluate unit training and the documentation of this training. HQ AFIA/SG will be tasked to provide HQ USAF/SGX with their findings from their biennial evaluations. Reserve unit training at their mobility site will be recommended at the next Annual Tour Allocation Conference, April 2001. Estimated date of completion: December 2002.

Page 25

USAF-12. Concur, with comment. Substantive. Page 20, Recommendation B.2. **Change to read:** "We recommend the Surgeons General of the Navy and Air Force require its blood program office to prepare mobilization planning documents that include establishing blood quotas and identifying mobilization staffing sources." **RATIONALE:** Eliminate contradictory statement and accurately reflect finding. **Corrective Actions:** At this time there are no mobilization staffing sources for the Air Force Blood Program Office. Augmentation positions have been advertised and, once filled, these will be added to the mobilization planning documents. Estimated date of completion: December 2002.

Revised
Page 26

The point of contact is Lt Col Fabrizio Saraceni, HQ USAF/SGXR, at (202) 767-5544.


KLAUS O. SCHAFER, Brig Gen, USAF, MC, CFS
Assistant Surgeon General, Readiness, Science & Technology
Office of the Surgeon General

U.S. Pacific Command Comments



**COMMANDER IN CHIEF, U.S. PACIFIC COMMAND
(USCINCPAC)**

CAMP H.M. SMITH, HAWAII 96861-4028

J053
7300
Ser 873-00

03 NOV 2000

To: Department of Defense Inspector General
(Attn: Ms. Betsy Brilliant, Readiness & Logistics Support Directorate)
400 Army Navy Drive, Arlington, VA 22202-2884

Subj: USCINCPAC COMMENTS TO THE DEPARTMENT OF DEFENSE INSPECTOR
GENERAL (DODIG) DRAFT AUDIT REPORT ARMED SERVICES BLOOD
PROGRAM READINESS (PROJECT NO. D2000LF-0028)

Ref: (a) DODIG ltr of 01 Sep 00

1. Reference (a) provides DODIG draft report for USCINCPAC review and comments..
2. The U.S. Pacific Command (USPACOM) concurs with the findings and recommendations of draft report with the following comments:

a. Findings are based upon operational plans and implementing instructions that are currently under revision. DOD approved planning process utilizing the Medical Analysis Tool has established a reduced PACOM blood requirement.

b. Staffing studies in collaboration with supported and supporting commands, the Service Blood Programs, and the Armed Services Blood Program establish that this revised requirement is well within the current capability of the Pacific Joint Blood Program organization utilizing the current Frozen Blood Program inventory.

3. Questions, if any, should be directed to the USCINCPAC project officer, LTC Birrer, J0714 at DSN (315) 477-7891 or commercial (808) 477-7891. The USCINCPAC audit liaison point of contact is Mr. Wayson Lee, J053 at DSN (315) 477-1182 or classified e-mail (leewc000@hq.pacom.smil.mil).

RONALD L. LOWE
Major General, USA
Deputy Chief of Staff

Copy to JS-J4

Audit Team Members

The Readiness and Logistics Support Directorate, Office of the Assistant Inspector General for Auditing, DoD, prepared this report. Personnel of the Office of the Inspector General, DoD, who contributed to the report are listed below.

Shelton R. Young
Michael A. Joseph
Betsy Brilliant
R. Thomas Briggs
Carol N. Gorman
W. Sterling Malcolm
Daniel S. Battitori
Daniel S. Bowers
Mark A. Vojtecky, Major, U.S. Air Force